

## Exhibit E

*Polymer Science and Materials Chemistry*

# Exponent®

**Wave 1 Supplemental Report  
Dr. Steven MacLean**

**United States District Court  
For The Southern District Of  
West Virginia  
Charleston Division**

**This document relates to:  
Ethicon Inc.,  
Pelvic Repair System  
Products Liability Litigation**

**Exponent®**

**Wave 1 Supplemental Report**

**Dr. Steven MacLean**

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF  
WEST VIRGINIA  
CHARLESTON DIVISION**

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## **Limitations**

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At the request of Butler Snow LLP, Exponent reviewed relevant scientific literature, historic documented studies and expert reports for the pending litigation. Exponent investigated specific issues relevant to this report as requested by the client. The scope of services performed during this investigation may not adequately address the needs of other users of this report, and any reuse of this report or its findings, conclusions, or recommendations is at the sole risk of the user. The opinions and comments formulated during this investigation are based on observations and information available at the time of the investigation.

The findings presented herein are made to a reasonable degree of scientific and engineering certainty. We have endeavored to be accurate and complete in our assignment. If new data become available or there are perceived omissions or misstatements in this report, we ask that they are brought to our attention as soon as possible so we have the opportunity to address them.

## **Steven MacLean, Ph.D., P.E. Biography**

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I am a Senior Managing Engineer in the Polymer Science and Materials Chemistry Practice at Exponent Failure Analysis Associates, Inc. (“Exponent”). My expertise and experience includes the chemical and physical behavior of polymeric materials in end-use applications, specifically in the evaluation of polymeric components in product safety assessments and product failure analysis. I have a B.S. and M.E. in Mechanical Engineering from Rensselaer Polytechnic Institute, and an M.S. in Material Science and Engineering from Rochester Institute of Technology. I also obtained a Ph.D. in Material Science from the University of Rochester in 2007. I am a registered Professional Engineer in New York and Maryland, a Senior Member of the Society of Plastics Engineers (SPE), and a board member of SPE’s Failure Analysis and Prevention Special Interest Group.

During the pursuit of my advanced degrees in materials science, my chosen field of study was polymer science and engineering. Graduate courses taken during my academic career that specifically focused on polymers included, but were not limited to, polymer science, organic polymer chemistry, polymer physics, polymer rheology, polymer processing, bulk physical properties of polymers, adhesion theory, and analytical techniques for polymeric materials. Supplemental course work included mechanics of materials, fracture mechanics, thermodynamics of materials and electron microscopy practicum. At the master’s degree level, my polymer research included characterizing the changes in chemical and physical properties of polycarbonate due to multiple heat histories from processing. At the doctoral level, my polymer research was focused on developing and investigating novel formulations of rubber-toughened polyphenylene ether polymers for use in pressurized, potable water systems. The primary emphasis of my dissertation included quantifying changes in select mechanical properties, including fracture toughness and tensile properties, due to the degrading effects from persistent exposure to chlorinated water at elevated temperatures.

In addition to my academic education and training, I have also been actively practicing in the field of polymer science and engineering for the past 20 years. Throughout that time, I have routinely utilized numerous polymer characterization techniques including, but not limited to, infrared spectroscopy, chromatography, mass spectrometry, calorimetry as well as optical,

scanning electron and transmission electron microscopy. In particular, I have used these microscopic techniques to examine the topography and morphology of fracture surfaces created as a result of polymer cracking. I have also employed these techniques to characterize modes of polymer failure such as creep, fatigue, stress overload, and environmentally assisted stress cracking. In many instances, I have published the use of these analytical techniques to investigate polymer failures in commercialized products in peer-reviewed journal articles and scientific conference proceedings.

Prior to joining Exponent in 2011, I worked for more than 15 years at General Electric Plastics (GE) and SABIC Innovative Plastics (SABIC) in a variety of technical roles of increasing responsibilities. Throughout my tenure, I was routinely involved in material selection, performance, and testing for, among other things, high-demand applications, product safety assessments, and product failure analysis. As a result, I have significant expertise and experience with industry standards and applicable regulations that prescribe the technical performance of polymeric materials in end-use applications, including those in the medical device industry.

At GE Plastics, I was trained extensively in the Six Sigma quality process, and became certified as a Six Sigma Black Belt. As a Certified Six Sigma Black Belt, my responsibilities included improving business processes by employing a variety of well-established statistical methods as well as mentoring and training Six Sigma Green Belts throughout the company.

Throughout my career, I have evaluated the suitability and performance of polymeric materials in end-use applications, including specifically, for the medical device industry. While at GE and SABIC, I worked with numerous medical device companies on material development, material specification, design and manufacturing for a wide variety of medical device applications. These efforts included, *inter alia*, developing and implementing tests related to the bulk physical properties of polymeric materials specified in said devices as well as material formulation development to meet unique device requirements that could not be met with off-the-shelf grades of resin. Formulation development often included the selection and refinement of base polymers or alloys, molecular weight, additives, stabilizers, processing aides, lubricants, colorants and inorganic fibers and fillers. In addition to proactive design and material selection assistance, I

have worked on hundreds of product safety assessments and failure analyses involving polymeric materials, many of which were performed on medical devices and components.

In my prior role as Director of Global Agency Relations and Product Safety at GE/SABIC, part of my leadership responsibilities included being an active member of the business' Healthcare Resins Advisory Board. The board developed internal processes and standards for the specification, use and sale of GE/SABIC resins in medical device applications. These efforts included ensuring that commercial resin grades within the GE/SABIC healthcare portfolio were assessed for biocompatibility using industry accepted test protocols such as United States Pharmacopeia (USP) Class VI, Tripartite Biocompatibility Guidance or ISO 10993 Biological Evaluation of Medical Devices standards. For the past several decades, the latter two standards have been supported by the Food and Drug Administration (FDA) and commonly employed to assess the potential for cytotoxicity, hemolysis, pyrogenicity, sensitization issues, among other biological effects, when the human body is exposed to foreign materials. In addition, the board also ensured that "good manufacturing processes" were globally implemented to maximize the purity levels of all compounded materials within the healthcare resin portfolio.

In addition to my relevant training, education and industry experience, I have also reviewed and synthesized the available public literature pertaining to *in vivo* and *in vitro* studies of polymeric mesh devices, long-term implantation of polymeric medical devices, foreign body response to implantable materials, as well as select plaintiff reports which allege *in vivo* PROLENE mesh degradation.

## Introduction

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### Motivation

Plaintiff's expert, Dr. Vladimir Iakovlev, opines that Ethicon's PROLENE mesh degrades *in vivo* based on a cracked layer observed on the outer surface of mesh after explantation. While this assertion has been made by other plaintiff's experts,<sup>1,2</sup> Dr. Iakovlev claims that the outer degradation layer is oxidized and "differs from the non-degraded core by its ability to trap histological dyes in the nanocavities produced in polypropylene due to degradation."<sup>3</sup>

Dr. Iakovlev bases his conclusions on flawed experiments in which he purports to show that oxidized, degraded PROLENE is stained using histological dyes such as Hematoxylin and Eosin (H&E). In previously conducted experiments, we demonstrated that purposefully oxidized PROLENE mesh samples—oxidized using two different methods—do not stain with the histological dyes H&E, contrary to Dr. Iakovlev's assertions. The purpose of this report is to show that our initial work is highly repeatable, because it holds true across five different PROLENE devices including three separate TVT devices (from two different lots), one hernia mesh device, and one suture. Polypropylene pellets were included as controls. Furthermore, as part of our experimental design and protocols, we also coated PROLENE devices with fetal bovine serum (FBS) as a positive control. FBS forms a protein-rich coating on the outside of PROLENE fibers that is stained by H&E whereas the underlying PROLENE fibers do not absorb stain, as expected. In this report, we further address the scientific deficiencies of Dr. Iakovlev's experiments and conclusions from a polymer science perspective. This report does not address issues related to histology<sup>4</sup> or Dr. Iakovlev's histological analysis.

### PROLENE Mesh and Sutures

Ethicon's antioxidant-stabilized polypropylene-based resin is known by its trademarked name PROLENE. The resin was determined to be "safe and effective for use" in nonabsorbable

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<sup>1</sup> Expert report of Dr. Howard Jordi dated 8-24-15, p. 13.

<sup>2</sup> Expert report of Dr. Scott Guelcher dated 8-24-15, p. 2.

<sup>3</sup> Expert report of Dr. Vladimir Iakovlev dated January 29, 2016, p. 18.

<sup>4</sup> Histology relates to the microscopic study of tissue. Here, I focus on the microscopic study of PROLENE polymer fibers, although the chemistry of histological staining is discussed from a background perspective.

surgical sutures by the FDA in 1969 and has been used ever since.<sup>5</sup> PROLENE sutures are manufactured by a melt spinning process.<sup>6</sup> In addition to sutures, Ethicon knits PROLENE filaments into mesh materials used in hernia repair and to treat pelvic organ prolapse and stress urinary incontinence.

## **PROLENE Composition**

As with many commercially available resin compounds, Ethicon's PROLENE resin is composed of several raw material ingredients in addition to the base isotactic polypropylene. The additional formulation ingredients and corresponding loading level ranges are:<sup>7</sup>

- Calcium stearate (0.25–0.35%) lubricant to help reduce tissue drag and promote tissue passage
- Santonox R (0.10–0.30%), a primary hindered phenol antioxidant
- Dilauralthiodipropionate (DLTDP, 0.40–0.60%), a secondary thioester antioxidant
- Procol LA-10 (0.25–0.35%) lubricant to help reduce tissue drag and promote tissue passage
- Copper phthalocyanate (CPC) pigment (0.55% max) colorant to enhance visibility (in blue filaments only)

A summary of the full resin history including information on compounding, manufacturing, and formulation changes can be found in John Karl's memo entitled "PROLENE Resin Manufacturing Specifications."<sup>8</sup>

## **Hematoxylin and Eosin (H&E) Stain**

Hematoxylin and Eosin, also referred to as H&E, are common stains used for illuminating components of cells and tissue, many of which are long molecules (polymers). The hematoxylin dye solution itself is a mixture of hematoxylin, hematein, aluminum ions, and solvent. It is used in combination with a "mordant" compound that helps link it to the tissue. This mordant is

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<sup>5</sup> NDA—4.16.1969 PROLENE FDA Approval (ETH.MESH.09625731-09625737).

<sup>6</sup> FDA—Reclassification.pdf (ETH.MESH.10665538—1065565).

<sup>7</sup> John Karl's January 23, 2003. Memo titled PROLENE Resin Manufacturing Specifications (Eth. Mesh.02268619–02268621).

<sup>8</sup> Ibid.

typically a metal cation, such as aluminum. This complex is cationic (positively charged) and can react with negatively charged, basophilic cell components, such as nucleic acids in the nucleus, rough endoplasmic reticulum, ribosomes, and acidic mucin. Eosin, used in combination with hematoxylin, is negatively charged and attracts positively charged molecules. It stains structures with positive charges, such as cellular membranes, cytoplasm, connective tissue, and extracellular matrix tissue.

Ionic bonding is the most important type of bonding that occurs during histological staining.<sup>9</sup> The mechanism for H&E “staining” of tissue is simple ionic bonding between two charges: charge on the H&E staining molecules and charges on the molecules that comprise the tissue. As an example, amino acids are the molecular building blocks of proteins (which are also polymeric), and some of these amino acids contain a charge, as shown in Figure 1.<sup>10</sup> These charged compounds will bind ionically<sup>11</sup> (charge to charge) with H&E molecules and appear stained. In summary, the published mechanism for how H&E stains is chemical, not physical, in nature. In other words, physical voids, cracks, or crevices in PROLENE (as posited by Dr. Iakovlev)<sup>12</sup> or other materials do not “trap” or hold H&E stain, especially once adequate washing and rinsing are performed.

Polypropylene or PROLENE molecules are not ionically charged and are therefore not expected to stain with H&E. Furthermore, as shown in my expert report, which discusses the pathways of polypropylene oxidation, oxidized polypropylene does not possess a distinct ionically charged region. Therefore, in accordance with not only first principles of polymer science, but also the accepted methodology and assessment routinely reported in the literature, oxidized polypropylene is also not expected to stain with H&E.

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<sup>9</sup> Veuthey, T., Herrera, G., & Dodero, V. I. (2014). Dyes and stains: from molecular structure to histological application. *Frontiers in bioscience (Landmark edition)*, 19, 91.

<sup>10</sup> Adapted from Dan Cojocari, University of Toronto, 2011, pKa Data, *CRC Handbook of Chemistry*, 2010.

<sup>11</sup> A common, familiar ionically bonded material is sodium chloride, or table salt, in which  $\text{Na}^+$  and  $\text{Cl}^-$  are bound together by ionic attraction.

<sup>12</sup> Expert report of Dr. Vladimir Iakovlev dated January 29, 2016, p. 18, 92, 93.

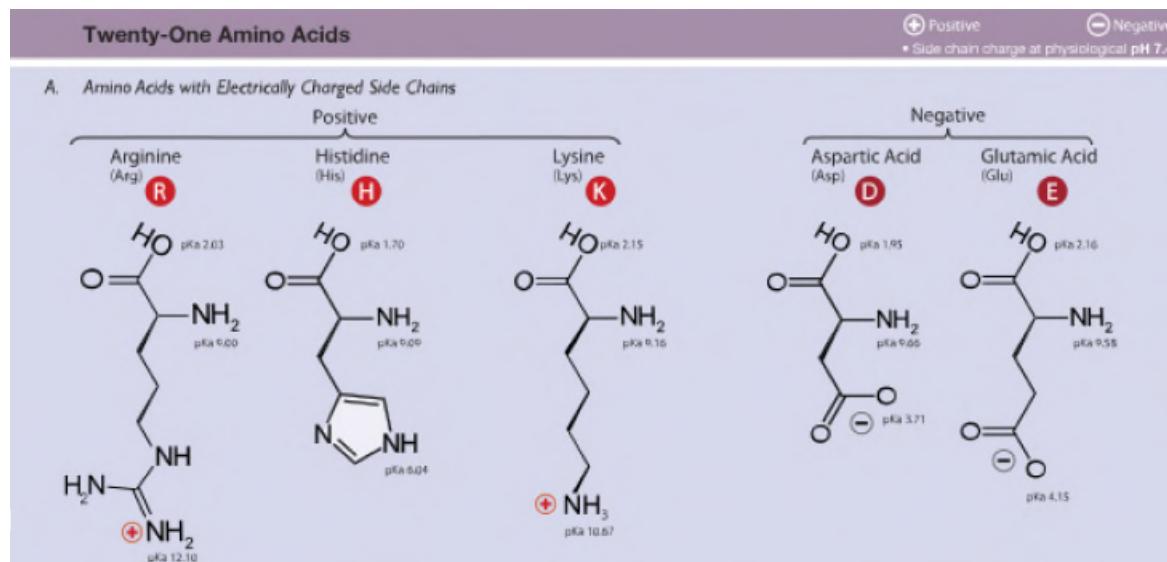


Figure 1. Amino acids that contain a net positive or negative charge.<sup>10</sup>

## **Experimental Investigation of the Capacity of PROLENE and Oxidized PROLENE to Accept H&E Stain**

I sought to investigate the capability of PROLENE and oxidized PROLENE to accept H&E stain since my review of the literature and first principles of polymer science did not explain the phenomenon observed and reported by Dr. Iakovlev. In my previous report, I demonstrated that intentionally oxidized PROLENE does not stain with H&E. In addition to my reliance on the literature and first principles of polymer science, I conducted a set of laboratory experiments to further validate my previous work that demonstrated that H&E does not stain PROLENE or oxidized PROLENE.

In the experiments reported herein, pristine (i.e., out-of-the-box, never implanted in the body), serum-coated, and purposefully oxidized PROLENE-based mesh and suture products were processed and subjected to histological dyes (Hematoxylin & Eosin) in accordance with protocols previously provided by plaintiff's expert Dr. Iakovlev. In expanding on experiments I have already carried out, multiple PROLENE devices were evaluated in these experiments. Specifically, to ensure repeatability, the following devices were examined:

- Ethicon PROLENE GYNECARE TVT™ Trans-Vaginal Tape Mesh Devices from two different lots
- Ethicon PHSE PROLENE Hernia System Extended Mesh Device
- Ethicon PROLENE 6-0 Blue Monofilament Suture

Rabbit tissue was included as a positive control for histological staining and polypropylene pellets that do not contain the same additive package (e.g., antioxidants, processing aids, or lubricants) as PROLENE in our analysis.

The above PROLENE devices and polypropylene pellets were subjected to the following preconditioning treatments prior to treating them with Dr. Iakovlev's staining protocol:

1. Photo-oxidation treatment by UV light<sup>13</sup>

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<sup>13</sup> QUV conditions employed here are the same UV conditions used in my microscopy report dated September 10, 2015.

2. Chemical oxidation solution treatment that reportedly degrades polypropylene<sup>14</sup>
3. Fetal bovine serum treatment as a protein-rich matrix

Pristine mesh was also included as a control. Preconditioning treatments are described in greater detail in later sections of this report. It is important to note that none of the materials included and examined here have been implanted in the body.

## **Sample Preparation Prior to Sectioning**

### **Exemplar PROLENE Samples**

Pristine PROLENE TVT mesh (Ethicon TVT Devices—Ref. No. 810041B, two devices from Lot Number 3859228 and one device from Lot Number 3832826), PHSE hernia mesh (Lot No. 27770-20), suture 6-0, and polypropylene resin pellets were received and kept in their original packaging until use. A clean razor blade was used to cut ~ 1 cm long sections of each sample for laboratory analysis (Table 1). Polypropylene pellets (Sigma-Aldrich, isotactic, average  $M_w$  ~340,000 , average  $M_n$ ~ 97,000) were used as received.

### **Chemically Oxidized PROLENE Samples**

Sections of PROLENE TVT meshes, PHSE hernia mesh, 6-0 suture, and polypropylene resin pellets were oxidized according to the protocol published by Guelcher and Dunn (Exponent protocol “Chemical Oxidation Protocol per Guelcher,” 1504469.000-5191).<sup>15</sup> Samples were incubated at 37°C for 5 weeks in oxidative media composed of 0.1 M CoCl<sub>2</sub> in 20 wt% H<sub>2</sub>O<sub>2</sub>. This solution purportedly simulates the oxidative environment created by macrophages in response to a foreign object.<sup>16</sup> The oxidative solution was changed every two to three days. Prior to processing, the samples were rinsed copiously in deionized water, then immersed in an ultrasonic bath (Exponent protocol “Rinsing Samples After Chemical Oxidation,” 1504469.000-7542). Samples were subsequently air-dried and assessed for visual appearance using optical microscopy and morphological changes using scanning electron microscopy (SEM).

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<sup>14</sup> Guelcher, S. A., & Dunn, R. F. (2015, June). Oxidative degradation of polypropylene pelvic mesh in vitro. International Urogynecology Journal. 26 (Suppl 1): S55-S56.

<sup>15</sup> Ibid.

<sup>16</sup> Ibid.

### **QUV-Oxidized PROLENE Samples**

Sections of PROLENE TVT meshes, PHSE hernia mesh, and suture 6-0 were placed inside a Q-Lab QUV Accelerated Weathering Tester and irradiated with  $0.98 \left(\frac{W}{m^2}\right)$  UV light at  $60^\circ\text{C}$  (Exponent protocol “QUV Oxidation Protocol for PROLENE,” 1504469.000-4837). Samples were imaged by SEM periodically and QUV exposure was stopped after extensive cracking was observed over the entire UV-exposed surface of the samples (5–12 days). Prior to being sent to a third-party lab for histological processing, the samples were assessed for morphological changes using SEM and optical microscopy.

### **Fetal Bovine Serum (FBS) Coated PROLENE Samples**

Sections of PROLENE TVT meshes, PHSE hernia mesh, suture 6-0, and polypropylene resin pellets were incubated in solutions of fetal bovine serum (FBS) at  $37^\circ\text{C}$  for six days (Exponent protocol “Serum Coated PROLENE Protocol,” 1504469.000-1151). After six days, the samples were removed from the serum, air-dried, assessed with optical microscopy and SEM, and immersed in a 10% formalin buffer solution for storage. Prior to being sent to a third-party lab for histological processing, samples were removed from formalin, air-dried, visually inspected for appearance using optical microscopy, and assessed for morphological changes using SEM.

**Table 1. PROLENE Samples for Sectioning**

	QUV Oxidized (Paraffin) <sup>17</sup>	QUV Oxidized (Resin)	Chemically Treated (Paraffin)	Chemically Treated (Resin)	Serum-coated (Paraffin)	Serum-coated (Resin)	(Out-of-the-box) Control (Paraffin)	Pristine Control (Resin)
<b>PROLENE TVT mesh Lot 3859228 #1</b>	ID: 157162 TVT Device Lot 3859228 #1 QUV-P	ID: 157163 TVT Device Lot 3859228 #1 QUV-R	ID: 157164 TVT Device Lot 3859228 #1 ChemOx-P	ID: 157165 TVT Device Lot 3859228 #1 ChemOx-R	ID: 157166 TVT Device Lot 3859228 #1 Serum-P	ID: 157167 TVT Device Lot 3859228 #1 Serum-R	ID: 157880 TVT Device Lot 3859228 #1 Control-P	ID: 157169 TVT Device Lot 3859228 #1 Control-R
<b>PROLENE TVT mesh Lot 3859228 #2</b>	ID: 157170 TVT Device Lot 3859228 #2 QUV-P	ID: 157171 TVT Device Lot 3859228 #2 QUV-R	ID: 157172 TVT Device Lot 3859228 #2 ChemOx-P	ID: 157173 TVT Device Lot 3859228 #2 ChemOx-R	ID: 157174 TVT Device Lot 3859228 #2 Serum-P	ID: 157175 TVT Device Lot 3859228 #2 Serum-R	ID: 157884 TVT Device Lot 3859228 #2 Control-P	ID: 157177 TVT Device Lot 3859228 #2 Control-R
<b>PROLENE TVT mesh Lot 3832826</b>	ID: 157178 TVT Device Lot 3832826 QUV-P	ID: 157179 TVT Device Lot 3832826 QUV-R	ID: 157180 TVT Device Lot 3832826 ChemOx-P	ID: 157181 TVT Device Lot 3832826 ChemOx-R	ID: 157182 TVT Device Lot 3832826 Serum-P	ID: 157183 TVT Device Lot 3832826 Serum-R	ID: 157895 TVT Device Lot 3832826 Control-P	ID: 157185 TVT Device Lot 3832826 Control-R
<b>PROLENE hernia mesh Lot 27770-20</b>	ID: 157186 Hernia Mesh Lot 27770-20 QUV-P	ID: 157187 Hernia Mesh Lot 27770-20 QUV-R	ID: 157188 Hernia Mesh Lot 27770-20 ChemOx-P	ID: 157189 Hernia Mesh Lot 27770-20 ChemOx-R	ID: 157190 Hernia Mesh Lot 27770-20 Serum-P	ID: 157191 Hernia Mesh Lot 27770-20 Serum-R	ID: 157899 Hernia Mesh Lot 27770-20 Control-P	ID: 157193 Hernia Mesh Lot 27770-20 Control-R
<b>PROLENE 6-0 suture</b>	ID: 157194 PROLENE 6-0 Suture QUV-P	ID: 157195 PROLENE 6-0 Suture QUV-R	ID: 159703 PROLENE 6-0 Suture ChemOx-P	ID: 159704 PROLENE 6-0 Suture ChemOx-R	ID: 157198 PROLENE 6-0 Suture Serum-P	ID: 157199 PROLENE 6-0 Suture Serum-R	ID: 157903 PROLENE 6-0 Suture Control-P	ID: 157201 PROLENE 6-0 Suture Control-R
<b>Polypropylene Pellet</b>	--	--	ID: 157232 Polypropylene pellet Sample #1	ID: 157233 Polypropylene pellet Sample #2	ID: 157234 Polypropylene pellet Sample #3	ID: 157235 Polypropylene pellet Sample #4	ID: 157236 Polypropylene pellet Sample #5	ID: 157237 Polypropylene pellet Sample #6

<sup>17</sup> The embedding material is listed parenthetically.

## Histology Sample Preparation

Exemplar, oxidized, and serum-coated mesh samples were embedded in both paraffin and resin (Technovit), sectioned, and stained with H&E. All processing was performed by an independent GLP-compliant<sup>18</sup> histology lab with more than 25 years of experience in histological processing of samples. Detailed embedding and staining protocols can be found in Appendix A.

Paraffin-embedded samples were prepared by following the protocol submitted by Dr. Iakovlev. Briefly, samples were sequentially dehydrated in reagent alcohol and xylene substitute using an automated tissue processor, and then embedded in Leica EM400 paraffin wax. Sections of the paraffin blocks (4–6 µm thick) were obtained using a microtome, briefly floated in a 40–45°C water bath, and mounted onto slides. Sections were air-dried for 30 minutes, then baked in a 45–50°C oven overnight.

Resin-embedded samples were sequentially dehydrated in reagent alcohol using an automated tissue processor and embedded in Technovit 7200. The polymerized resin block was trimmed. Then sections were cut and ground to a thickness of 10–61µm with a mean thickness of approximately 30 µm.

Paraffin and resin-embedded samples were subjected to staining with H&E. All slides were imaged by Exponent personnel using a microscope equipped with polarizing filters.

## Results

### Scanning Electron Microscopy of PROLENE and Polypropylene Samples

All samples listed in Table 1 were imaged with SEM prior to histological processing and microscopy evaluation (Figure 2). To observe surface features clearly, images of mesh samples were obtained at 100× magnification. Representative images of 6-0 suture samples were obtained at 200× magnification (Figure 3).

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<sup>18</sup> Per 21 CFR Part 58 – Good Laboratory Practice for Nonclinical Laboratory Studies.

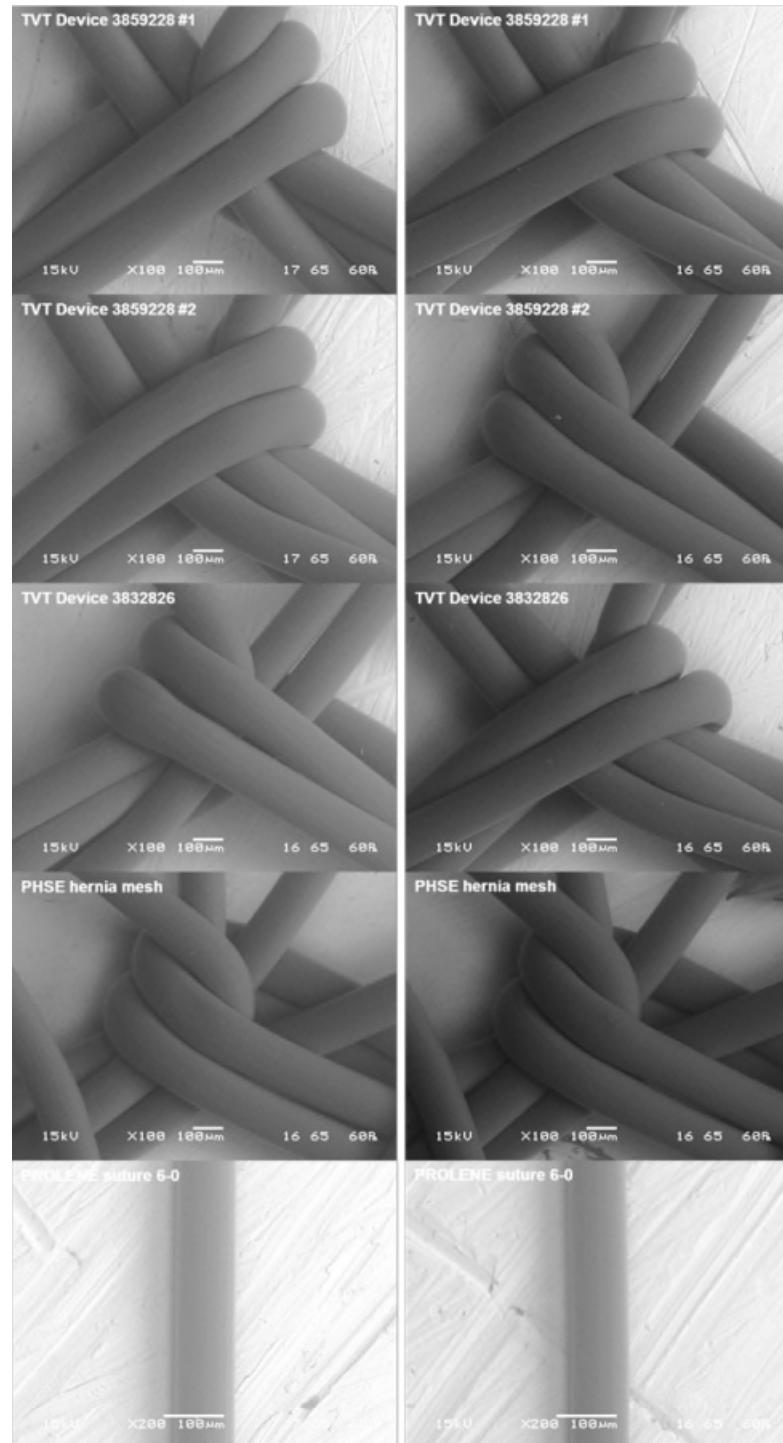


Figure 2. SEM images of pristine untreated samples. Left column: samples intended for paraffin mounting, sectioning, and staining as part of following Dr. Iakovlev's protocol. Right column: samples intended for resin mounting, sectioning, and staining.<sup>19</sup>

<sup>19</sup> The images were brightened during post-processing to enhance contrast.

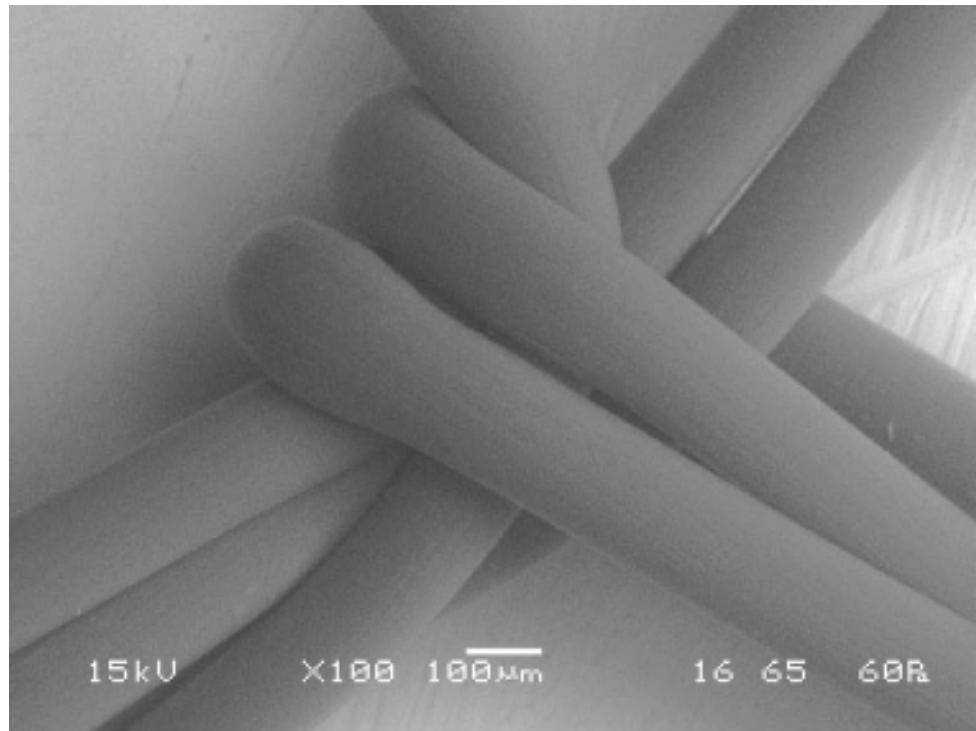


Figure 3. SEM image of a representative pristine TTV mesh sample prior to being subjected to Dr. Iakovlev's histological processing protocol.<sup>20</sup>

As expected, the sample surfaces of pristine untreated PROLENE TTV devices, PHSE hernia mesh, and 6-0 suture appeared smooth and uniform, with no apparent defects or cracking. The surface of the polypropylene pellet, as imaged by SEM, was similarly smooth and uniform, with no apparent defects (Figure 10A).

The surfaces of chemically oxidized samples were similarly smooth and uncracked (Figure 4). However, several crystals, likely inorganic, cobalt-based crystals, were observed to be well-adhered to the surface of the PROLENE samples after exposure to the chemical treatment protocol as shown in Figure 5.

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<sup>20</sup> Ibid.

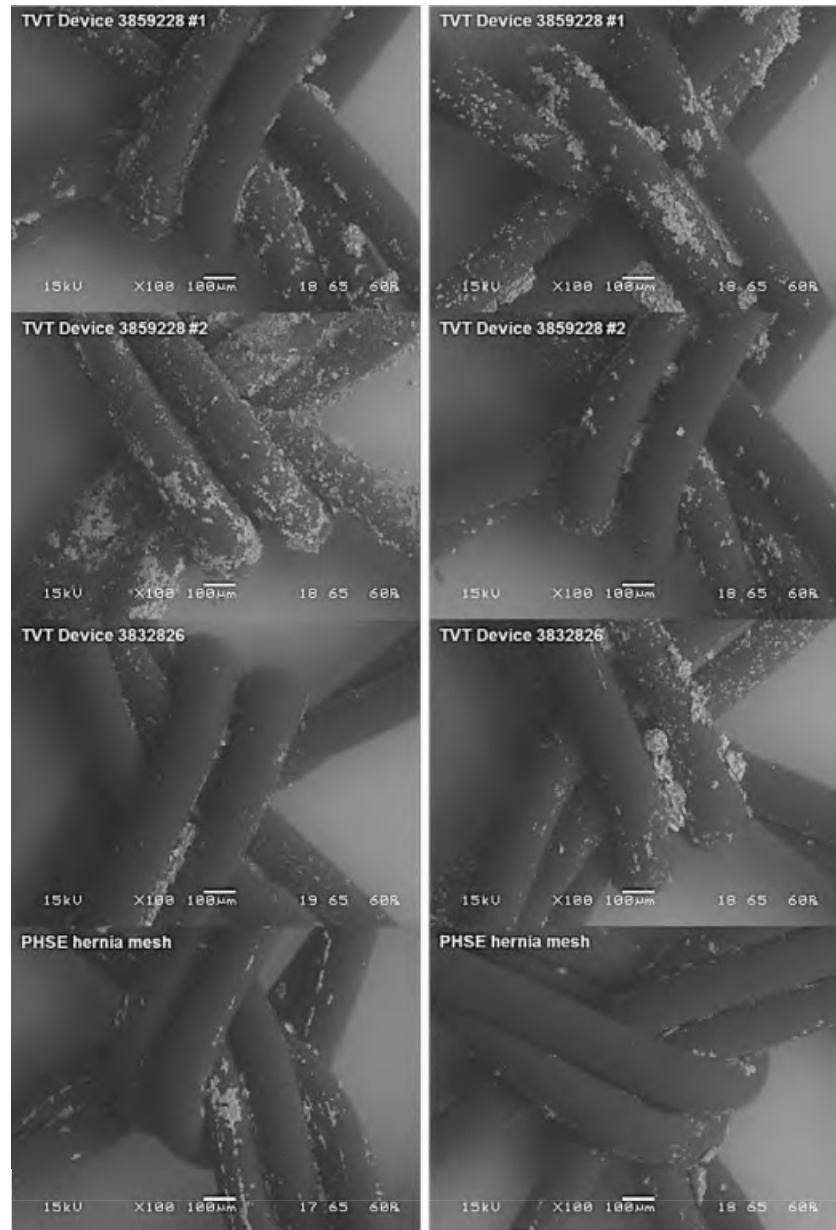


Figure 4. SEM images of chemically treated samples. Left column: samples intended for paraffin mounting, sectioning, and staining per Dr. Iakovlev's protocol. Right column: samples intended for resin mounting followed by staining with H&E.

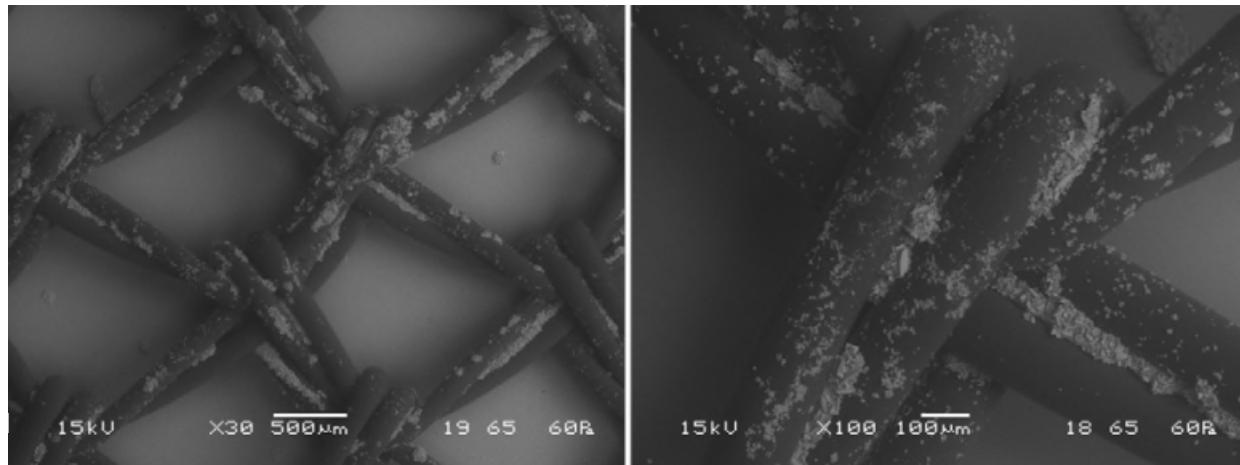


Figure 5. SEM images of an area of a TTV device after exposure to chemical treatment.

These observations differ from the results published by Guelcher and Dunn, who reported “pitting” and “flaking” in polypropylene meshes subjected to the same treatment conditions.<sup>14</sup> The light-colored crystallite material not removed during the rinsing procedure (Exponent protocol “Rinsing Samples After Chemical Oxidation,” 1504469.000-7542) and observed on the surface of the samples is consistent with cobalt-based crystallite deposits according to energy dispersive X-ray spectroscopy (EDS) analysis. EDS was performed on two areas of a representative mesh sample (TTV Device 3859228 #1) after chemical oxidation treatment. EDS measurements revealed that the PROLENE surface was composed predominantly of carbon, and that the light-colored crystals were predominantly composed of cobalt (Figure 6).

In contrast to the pristine (untreated control) and chemically treated samples, QUV-oxidized samples exhibited extensive cracking covering most of the mesh and suture surfaces. A representative image illustrating the extensive cracking observed over most of the surface is shown in Figure 7. Longitudinal cracks with length scales of several hundreds of microns were observed traversing the length of the mesh fibers. Accompanying radial cracks, with length scales on the order of 100 microns or less, were observed perpendicularly to the longitudinal cracks. The extent of cracking was uniform across the five different PROLENE devices examined (Figure 8).

Prior to embedding, cross-sectioning, and staining per Dr. Iakovlev’s protocol, the serum-coated samples were also imaged with SEM. The proteinaceous coating deposited on the surface of PROLENE mesh samples treated with FBS can be seen clearly with SEM (Figure 9). The

coating had a sheet-like appearance that concentrated predominantly in the areas between the mesh fibers. However, the PROLENE surfaces themselves were uncracked and smooth, and similar to pristine untreated samples. A thin layer of the proteinaceous coating was also observed on the surface of 6-0 suture samples and polypropylene pellet samples (Figure 10c and Figure 11c).

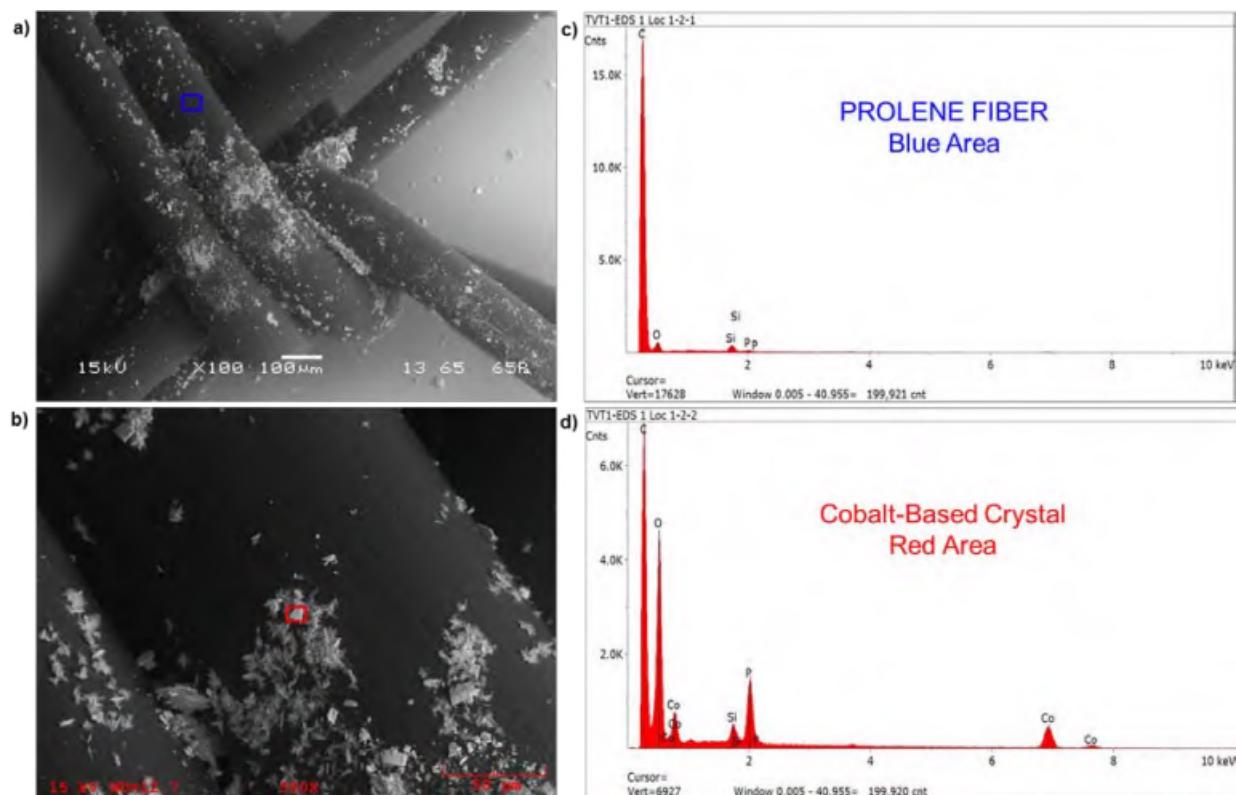


Figure 6. SEM images with corresponding EDS analysis areas performed on TVT Device 3859228 #1 after chemical treatment.<sup>21,22,23</sup> (a) SEM image of mesh, (b) 500x magnification of mesh fiber, (c) EDS elemental profile of mesh fiber surface, (d) EDS elemental profile of light-colored crystals.

<sup>21</sup> Guelcher, S. A., & Dunn, R. F. (2015 June). Oxidative degradation of polypropylene pelvic mesh in vitro. International Urogynecology Journal 26 (Suppl 1): S55-S56.

<sup>22</sup> Exponent protocol “Chemical Oxidation Protocol per Guelcher,” 1504469.000-5191.

<sup>23</sup> Exponent protocol “Rinsing Samples After Chemical Oxidation,” 1504469.000-7542.

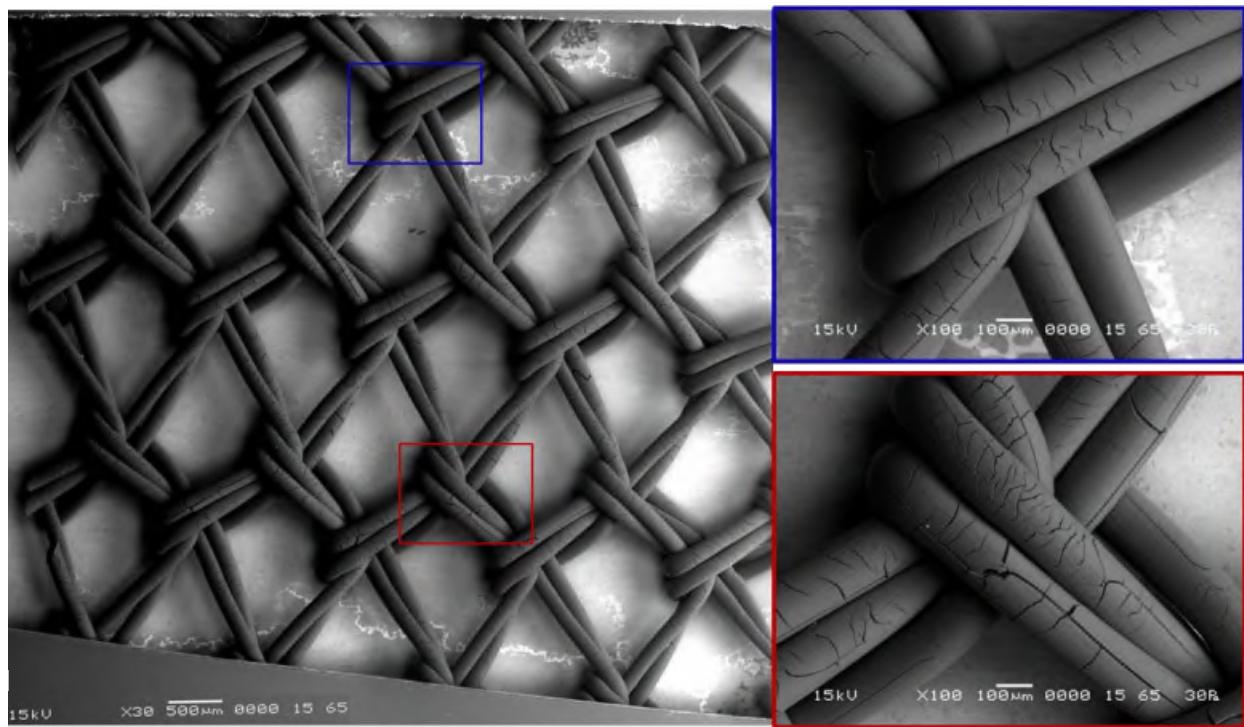


Figure 7. SEM images of QUV-oxidized TVT Device 3859228 #1 resin sample. Left: representative overall image at 30 $\times$  magnification. Right: representative images at 100 $\times$  magnification.

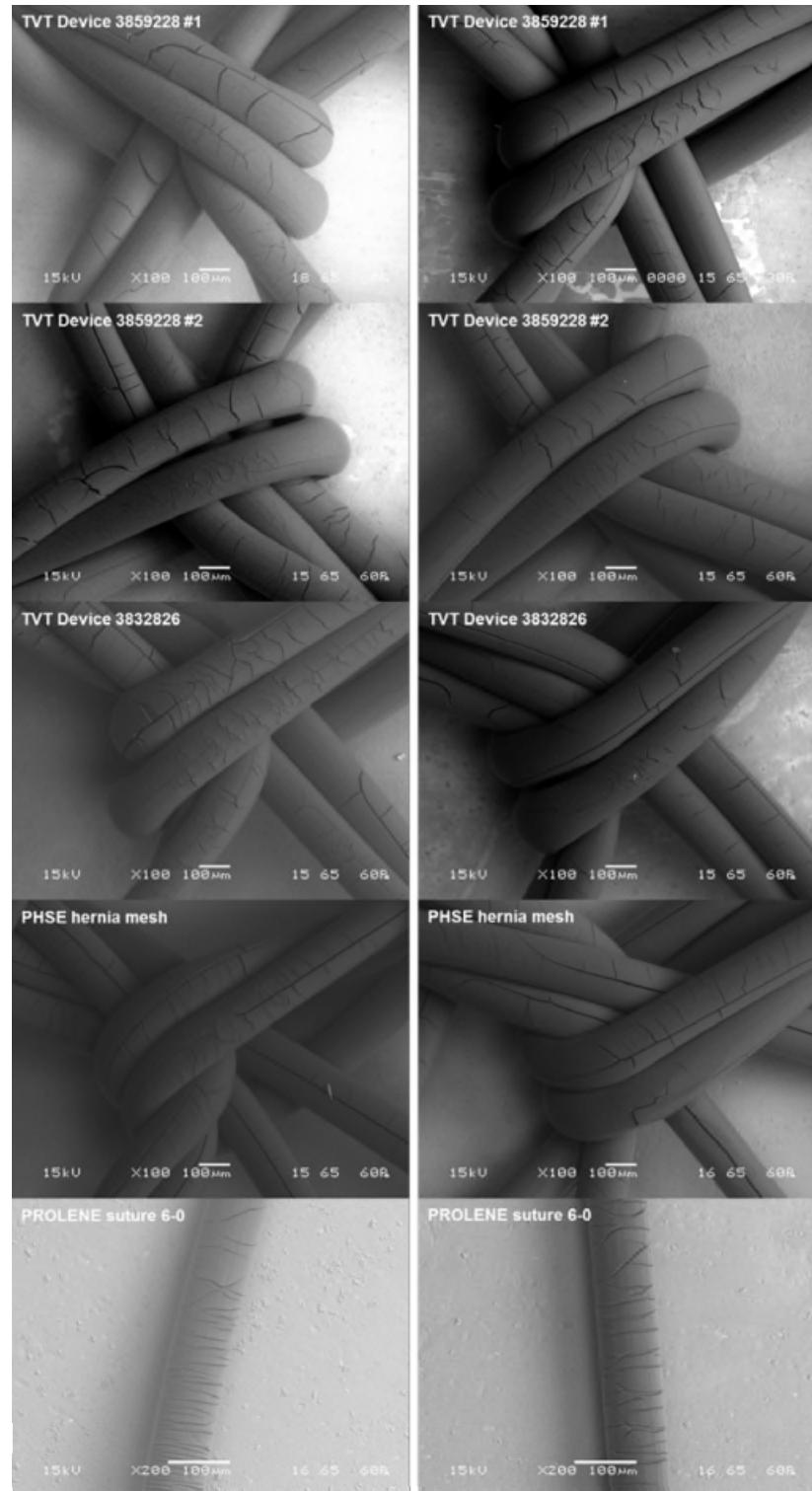


Figure 8. SEM images of representative areas of QUV-oxidized samples. Left column: samples intended for paraffin mounting, sectioning, and staining according to Dr. Iakovlev's protocol. Right column: samples intended for resin mounting. Longitudinal and radial cracks are observed over the entire surface.

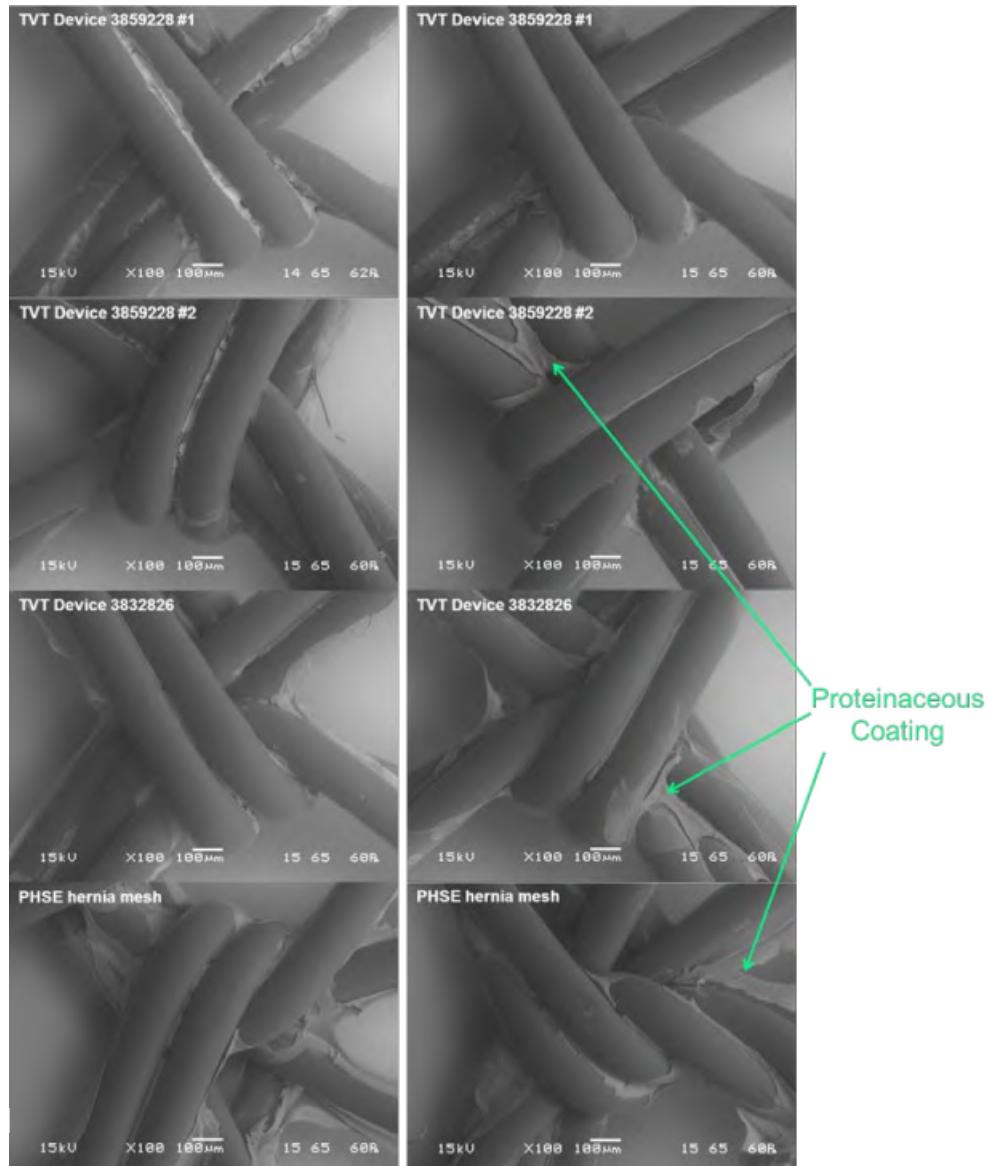


Figure 9. SEM images of serum-coated samples. Left column: samples intended for paraffin mounting, cross-sectioning, and staining according to Dr. Iakovlev's protocol. Right column: samples intended for resin embedding. Green arrows indicate examples of proteinaceous coating and cracks within the coating.<sup>24</sup>

<sup>24</sup> The images were brightened during post-processing to enhance contrast.

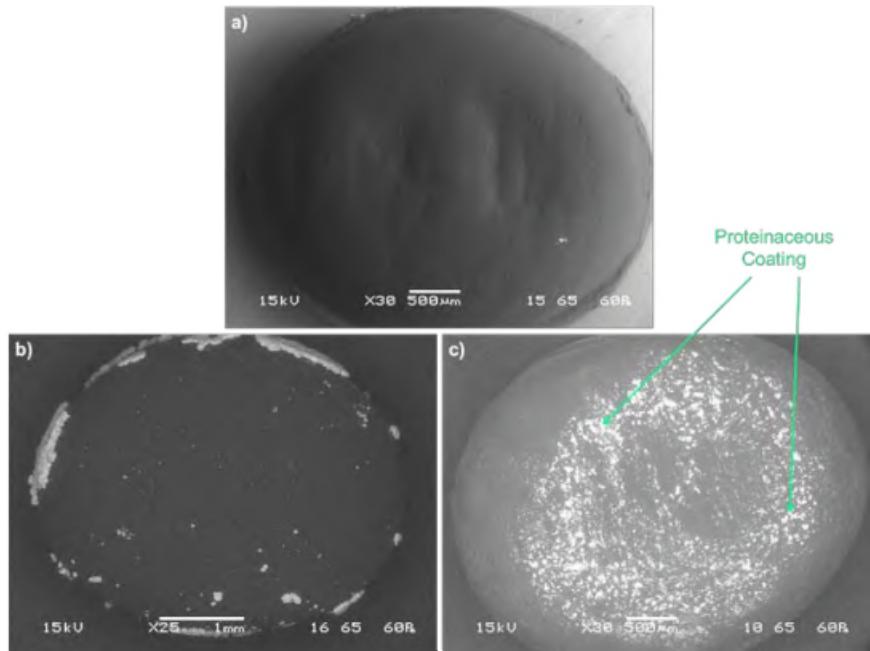


Figure 10. SEM images of polypropylene pellets intended for paraffin mounting. (a) Pristine sample, (b) chemically oxidized sample, and (c) serum-coated sample.<sup>25</sup>

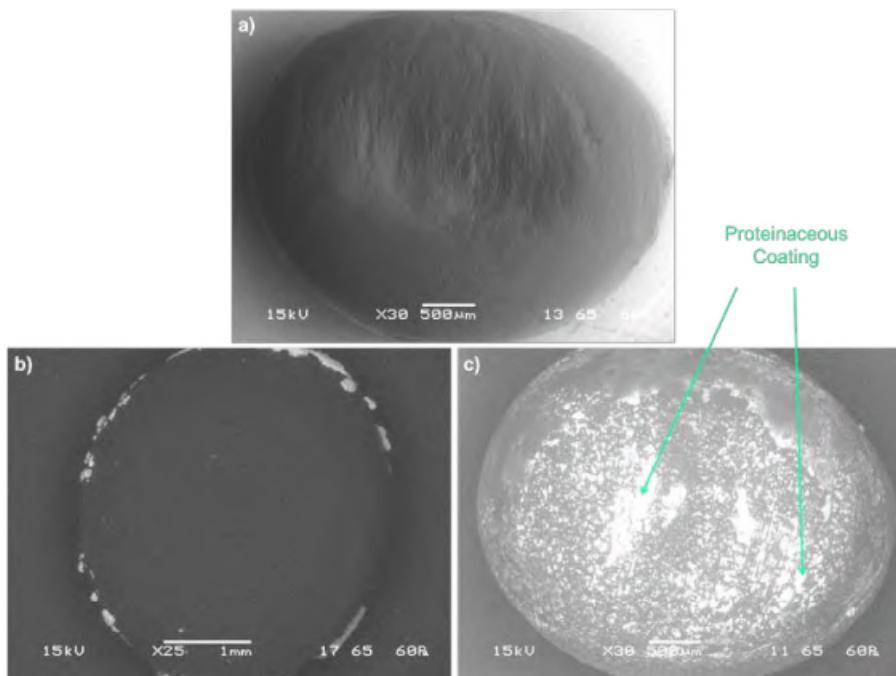


Figure 11. SEM images of polypropylene pellets intended for resin mounting. (a) Pristine sample, (b) chemically oxidized sample, and (c) serum-coated sample. Samples intended in for resin mounting.

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<sup>25</sup> The images were brightened during post-processing to enhance contrast.

## Fourier Transform Infrared Spectroscopy (FTIR) Analysis of Intentionally Oxidized Samples

Small segments of the chemically treated and UV-oxidized samples listed in Table 1 were analyzed by Fourier transform infrared spectroscopy (FTIR) to potentially identify functional groups consistent with oxidation. FTIR spectra were acquired on a pristine PROLENE sample for comparison. In the UV-treated and chemically treated samples, we observed bands consistent with hydroxyl (OH) bands and carbonyl (C=O) bands that can be indicative of oxidation. These bands were not observed in the pristine samples. Representative spectra are shown in Figure 12.

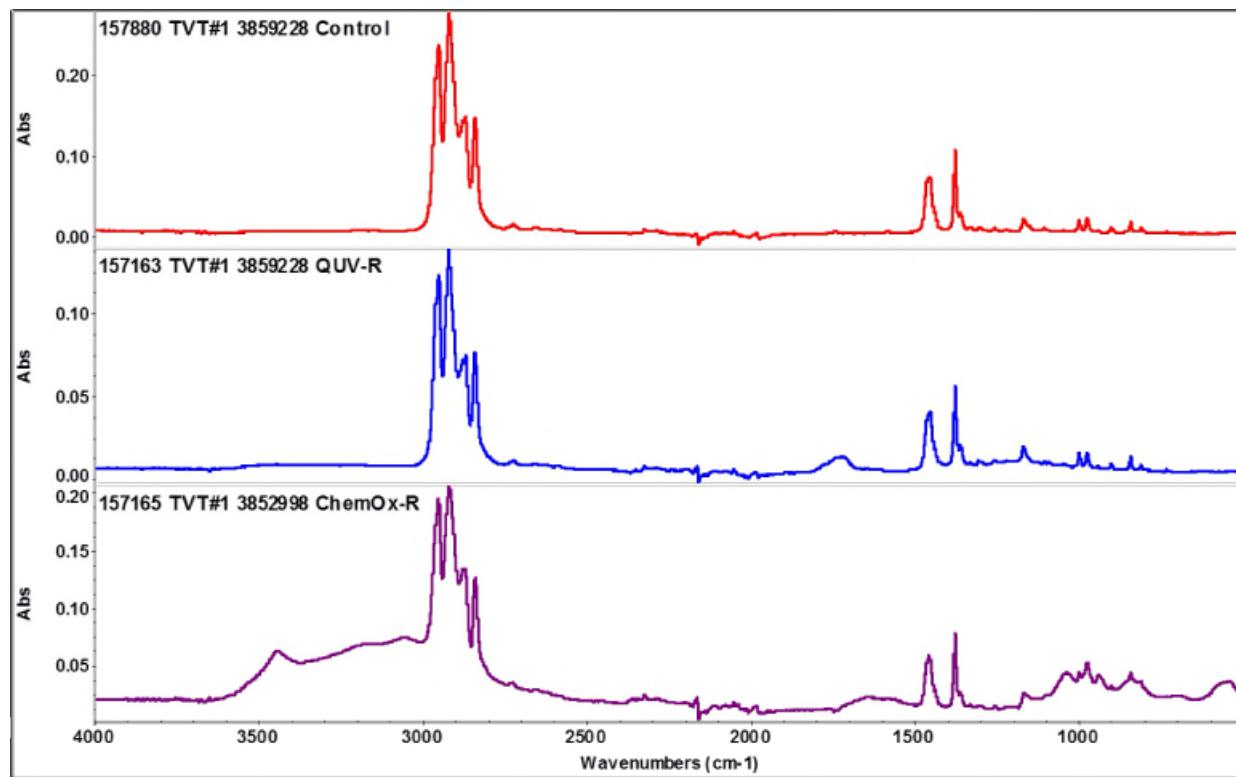


Figure 12. FTIR spectra of a pristine (untreated control) TTV mesh sample, QUV-treated sample, and chemically treated sample. Bands consistent with –OH groups ( $\sim 3000 \text{ cm}^{-1}$  –  $3500 \text{ cm}^{-1}$ ) and C – O groups ( $1600 \text{ cm}^{-1}$  –  $1760 \text{ cm}^{-1}$ ) are observed in the treated samples but not in the pristine samples.

## **Intentionally Oxidized PROLENE TVT and Hernia Mesh Devices, Sutures, and Polypropylene Pellets Were Not Stained by the Hematoxylin & Eosin Dyes**

### **Positive Control: Rabbit Skin Tissue**

A positive control (rabbit skin tissue) was processed to demonstrate the effectiveness of the processing and staining protocol. PROLENE meshes and sutures, treated and untreated, along with the polypropylene pellets, were subjected to the staining protocol at the same time.

The appearance of stain is evident when tissue is present and stain has been applied. Figure 13 shows rabbit tissue that has been treated with stain, evident by the coloration within the tissue. These results confirm that the staining protocol employed in these experiments is effective in staining proteinaceous materials.

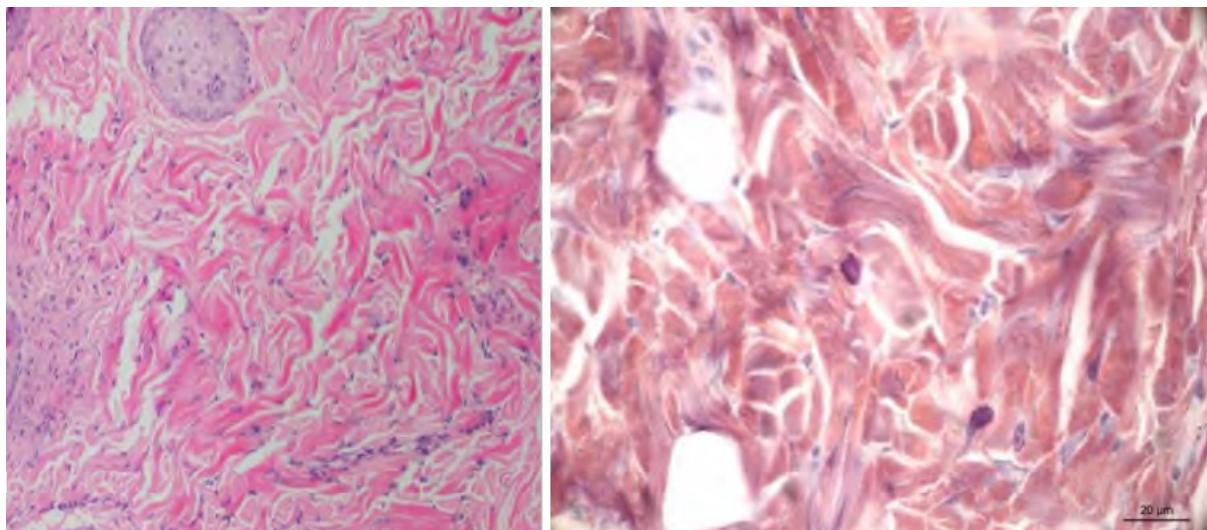


Figure 13. Processed and sectioned tissue that has been subjected to the staining protocol and is modified by the H&E stain. Representative images of rabbit tissue embedded in paraffin (left) and resin (right) are shown.<sup>26</sup>

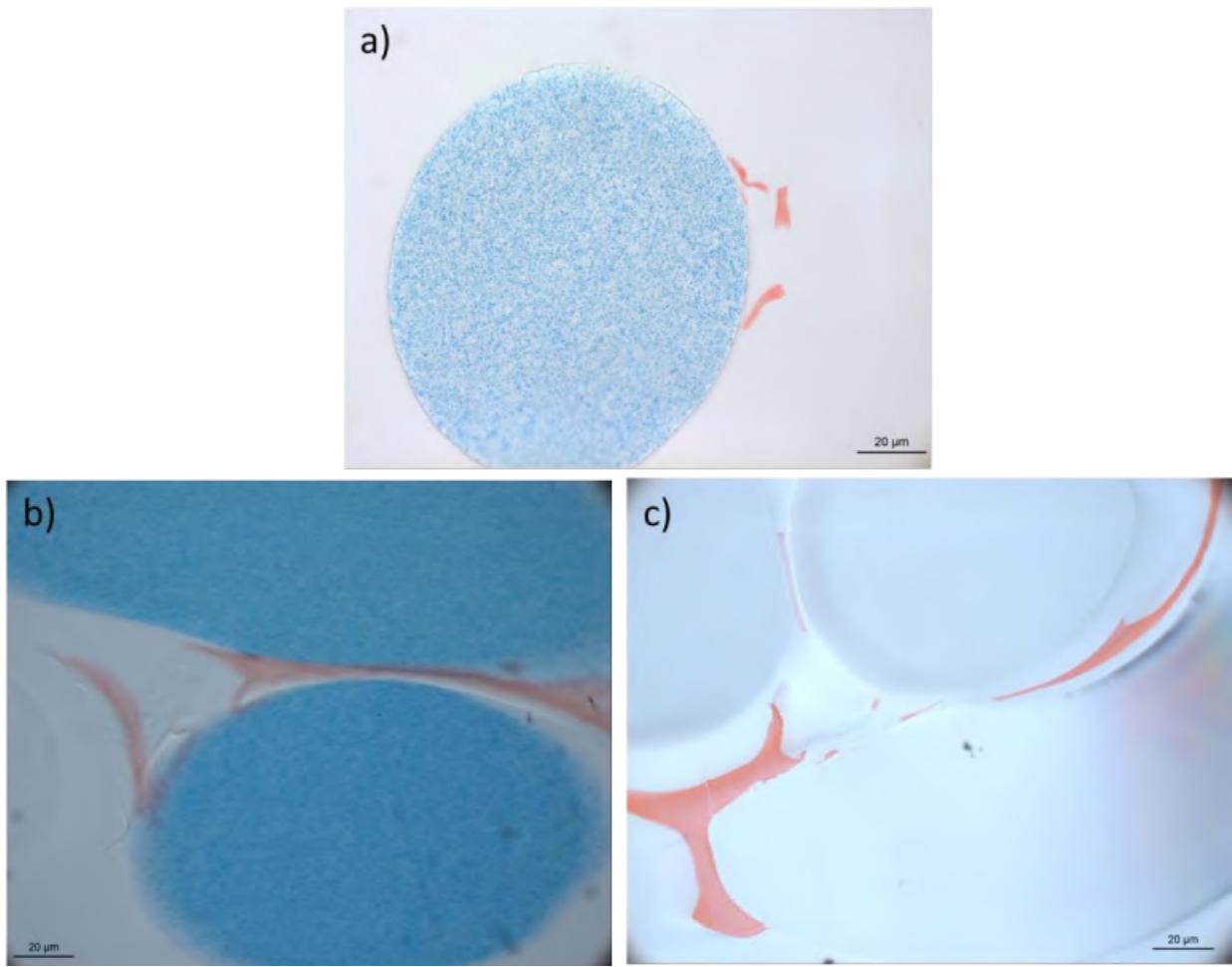
### **Serum-Coated PROLENE—PROLENE with Protein-Rich Coating**

PROLENE coated with FBS and stored in formalin was also subjected to the staining protocol. The protein-rich serum coating around the pristine PROLENE mesh was found to stain, as expected, while the PROLENE fiber itself did not stain. The color of the stain on the serum coating is similar to that of the positive control of rabbit skin. Representative images of serum-

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<sup>26</sup> All images collected as part of our experiments are given as an Appendix to this report.

coated TVT and hernia mesh are shown in Figure 14. In Figure 14b, a segment of serum is observed adjacent to the bottom of the PROLENE fiber in the top half of the image. Upon closer inspection, blue granules are visible within the serum coating, creating an illusion that blue granules are present in the exterior coating, when really they are separate, distinct materials. The illusion is created by both the fiber and serum segment being partially in focus. Additional examples that demonstrate this effect are given in Figure 15. Figure 15A shows the fiber in focus; the serum segment overlaid with the fiber is not. However, blue granules from a PROLENE fiber are visible within the protein-rich serum coating or “bark” as Dr. Iakovlev asserts, giving the illusion of stained PROLENE.<sup>27</sup>



**Figure 14.** Serum-coated PROLENE fibers. (a) Paraffin embedded and (b) resin embedded are from TVT devices. (c) Resin embedded is from a hernia device. All samples were subjected to the staining protocol.

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<sup>27</sup> Expert report of Dr. Vladimir Iakovlev dated January 29, 2016, p. 88, 94.

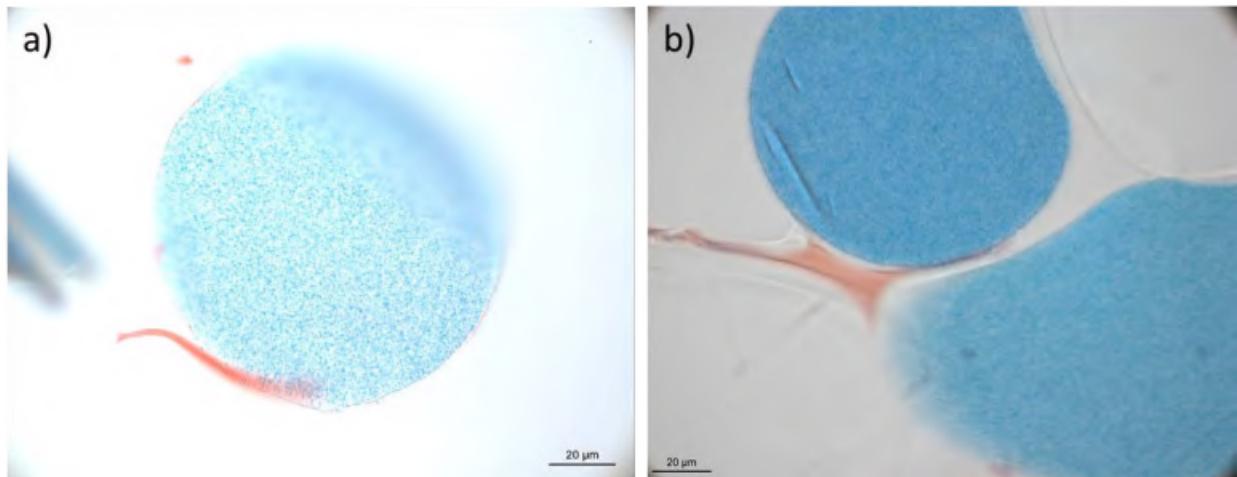


Figure 15. Blue granules from a PROLENE fiber are visible within the protein-rich serum coating, giving the illusion of stained PROLENE.

#### **Non-oxidized Control—Out-of-the-Box PROLENE Mesh**

In contrast, pristine PROLENE material processed using the same protocol and subjected to H&E staining protocol did not stain. The absence of staining is indicated by the absence of any pink coloration of the mesh fibers in samples embedded in either paraffin or resin (Figure 16).

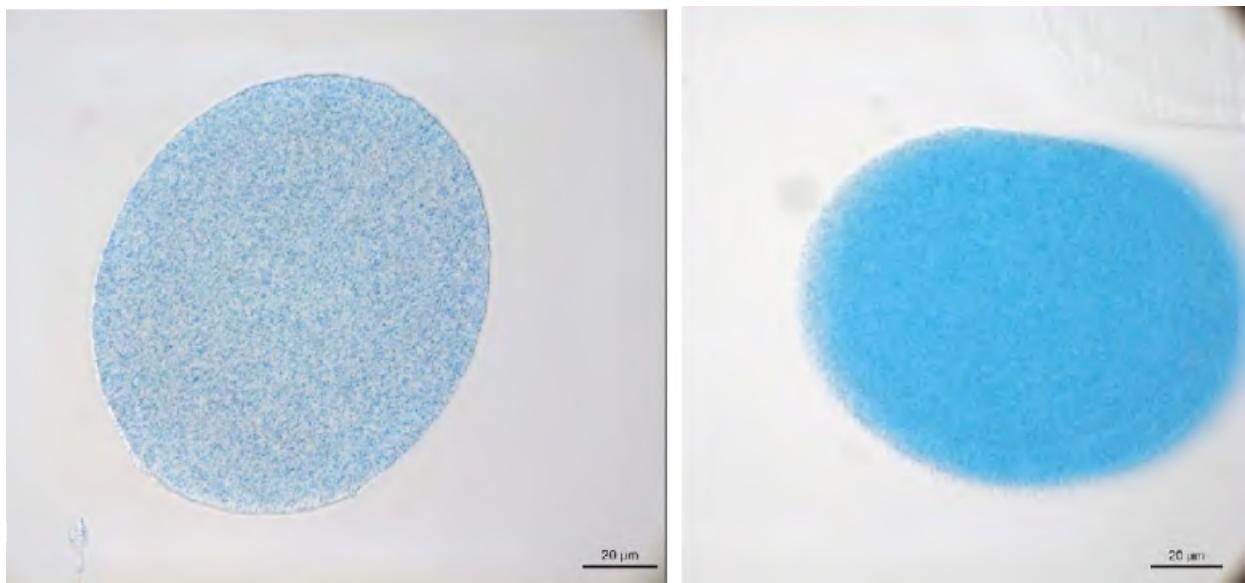


Figure 16. Pristine mesh fiber embedded in paraffin and subjected to Dr. Iakovlev's protocol (left). Pristine mesh fiber embedded in Technovit resin and subjected to staining (right). Both samples show an absence of H&E dye being absorbed.

### **Intentionally Oxidized PROLENE—Chemical Oxidation**

The chemically treated PROLENE was not modified by the H&E stain in any of the five PROLENE devices examined, thereby confirming the flawed methodology of Dr. Iakovlev. The cobalt-based crystallites observed to cover the fiber surface when imaged with SEM appeared to be preserved in the cross-sections. The crystals that coat the surface of the PROLENE fibers appear pink. They also appear pink/purple in micrographs taken after the samples were embedded in paraffin and sectioned but before they were subjected to the staining protocol, as shown in Figure 17. The pink color appears enriched in the image of the stained fiber, likely because cobalt chloride is an ionic compound and therefore susceptible to accepting H&E stain.

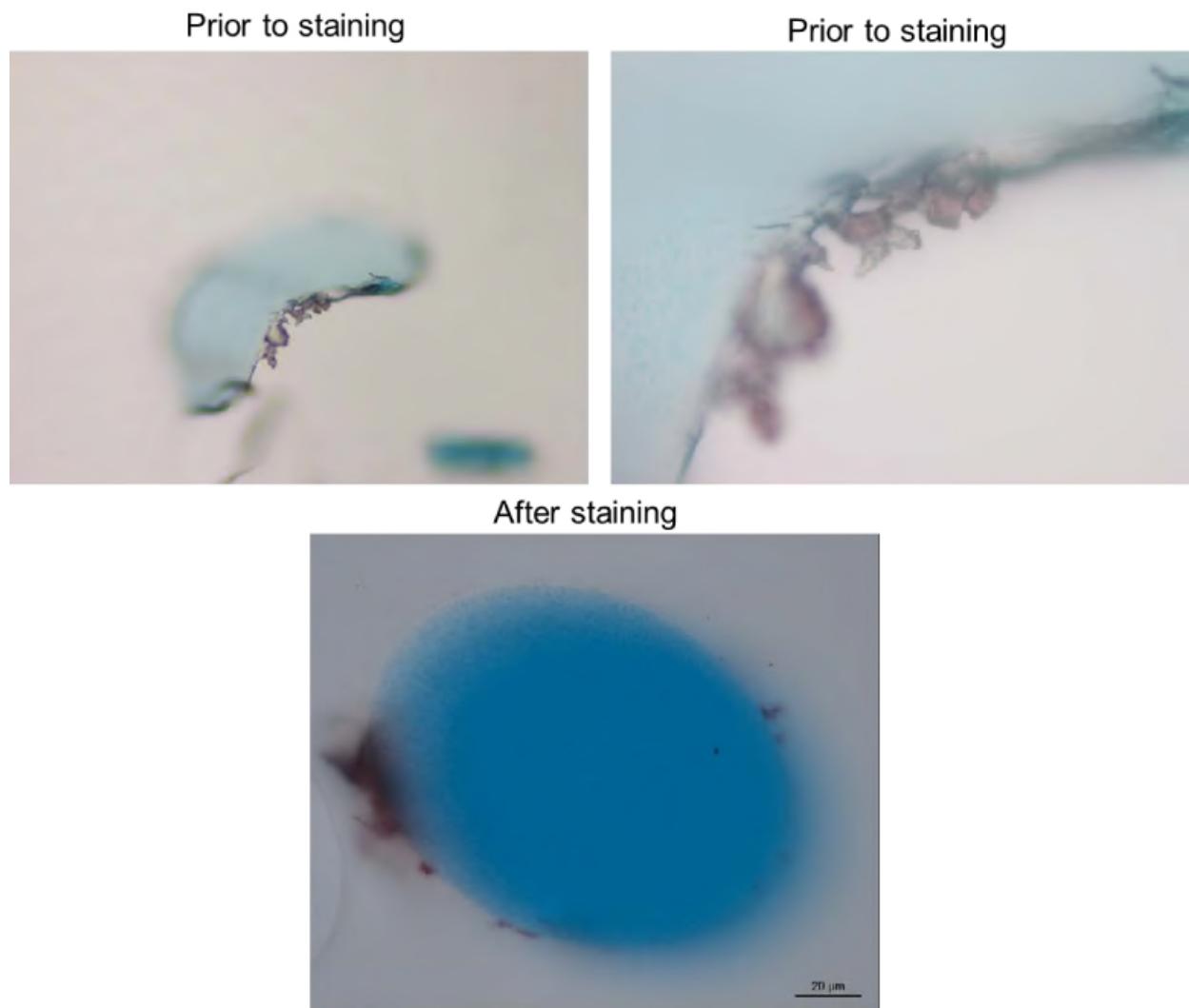


Figure 17. Cobalt-based crystallites adhered to the fiber surface are observed to be pink prior to being exposed to stain and after being stained.

Furthermore, cobalt-based crystallites appeared to be easily lodged between mesh fibers embedded in resin. An example is shown in Figure 18. An image of the fibers illuminated under cross-polarized light is also shown.

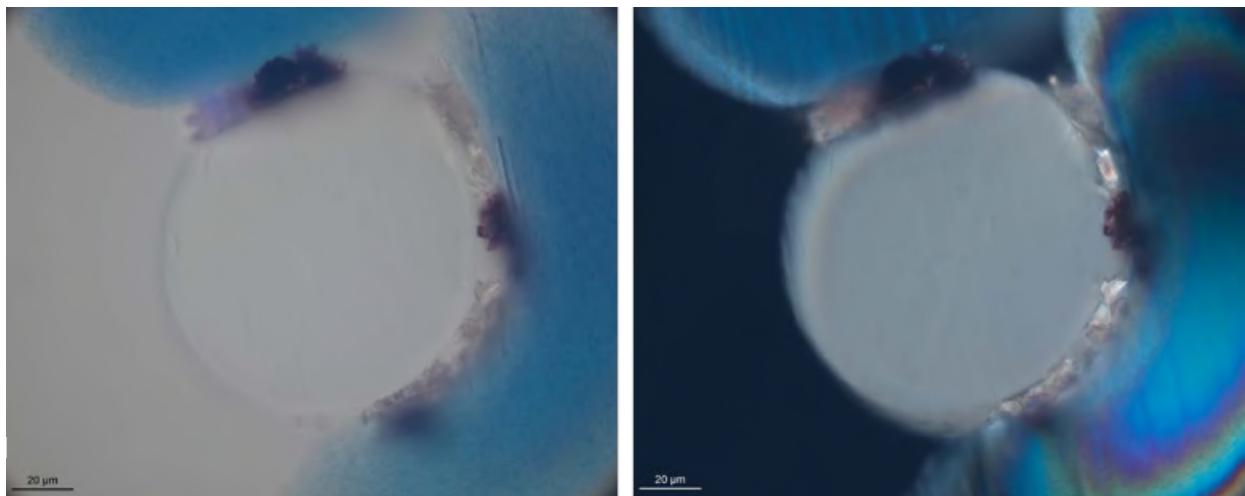


Figure 18. Cobalt-based crystallites are lodged between fibers. A bright field image is shown (left) as well as an image of the same fibers under cross-polarized light (right).

#### **Intentionally Oxidized PROLENE—UV Oxidation**

Exemplar PROLENE mesh samples exposed to QUV oxidation were also subjected to the Iakovlev staining protocol. As shown in Figure 19, despite the fact that fibers are extensively cracked and should have trapped stain, according to Dr. Iakovlev, the QUV-oxidized PROLENE did not accept the H&E stain. This finding further supports the conclusion that Dr. Iakovlev's methodology is flawed. Despite multiple observations, using high and low magnifications, polarized and nonpolarized light, no evidence of the stain being trapped, captured, or otherwise bound within the cracks of the damaged mesh was observed in any of the five different PROLENE devices examined.

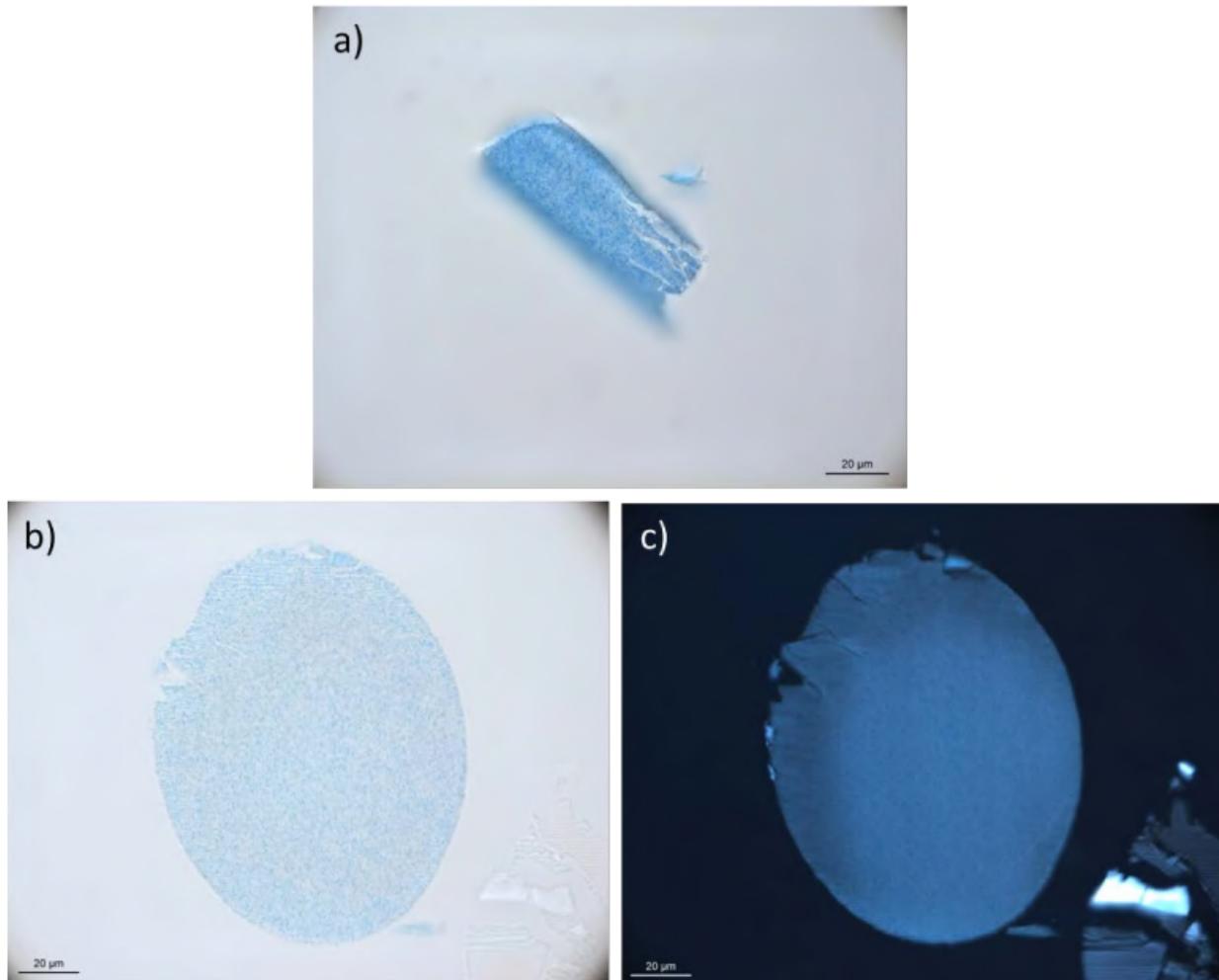


Figure 19. QUV-oxidized PROLENE fibers with several cracks embedded in paraffin. No staining is evident. Mesh fibers are shown under bright field light (a) and (b) and illuminated under cross-polarized light (c).

## Imaging Artifacts

Microtome slicing of polymeric samples is a technique that I am familiar with and has been used in the field of polymer science for decades.<sup>28,29,30</sup> Observation of thin-sliced polymeric specimens, including those that have been dyed, requires an understanding of potential artifacts that can exist as a result of the cutting process.

<sup>28</sup> Wang, X., & Zhou, W. (2002). Glass transition of microtome-sliced thin films. *Macromolecules*, 35(18), 6747–6750.

<sup>29</sup> Stiftinger, M., Buchberger, W., & Klampfl, C. W. (2013). Miniaturised method for the quantitation of stabilisers in microtome cuts of polymer materials by HPLC with UV, MS or MS<sub>2</sub> detection. *Analytical and bioanalytical chemistry*, 405(10), 3177–3184.

<sup>30</sup> Janeschitz-Kriegl, H., Krobath, G., Roth, W., & Schausberger, A. (1983). On the kinetics of polymer crystallization under shear. *European polymer journal*, 19(10), 893–898.

In some instances during this study, select images appeared to have a pink background when viewed on two separate computer monitors. An example of this is shown in Figure 20. The image on the left is the actual image file. The image on the right is a photograph of the same image file being displayed on a different monitor. A photograph was taken to capture the color difference. This perceived change in hue is one example of how optics, lighting, and related artifacts may influence visual observations.

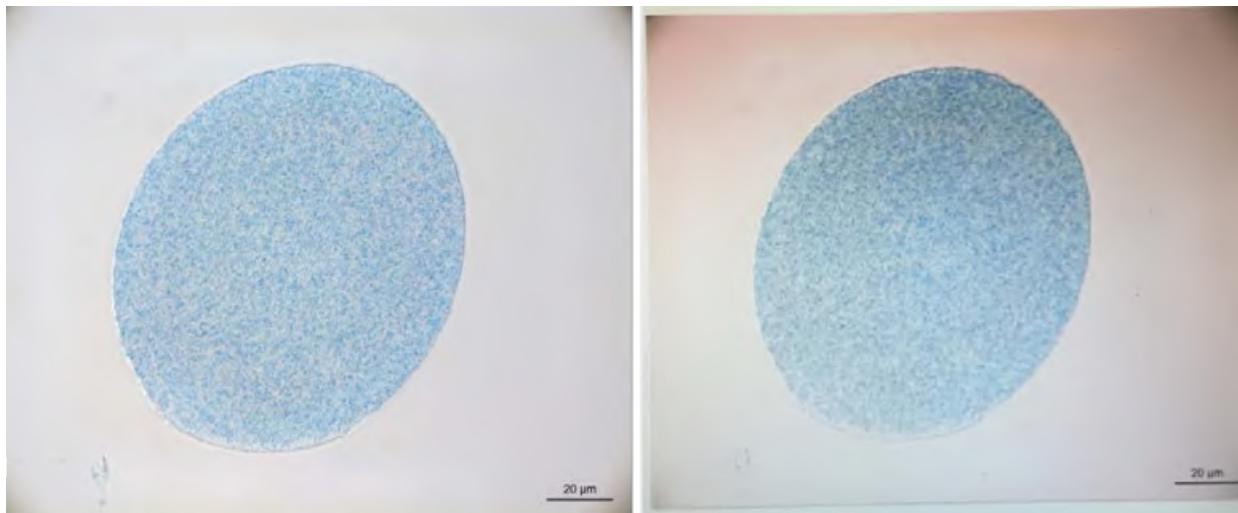


Figure 20. Same micrograph image of pristine PROLENE shown on two different computer monitors. A photograph of the image on the screen of monitor 2 was taken to preserve the observed pink coloring artifact.

### **Thickness Variation and Stain Pooling**

When high-aspect ratio samples (such as fibers) are sectioned with a microtome, simple geometry dictates that the thickness will be variant if the microtome knife is not orthogonal to the sample's long axis. This geometric artifact is exhibited schematically in Figure 21, which illustrates that the edges of the sliced specimen are thinner when viewed under the microscope.

This same effect can result in stain pooling, which is also illustrated schematically in Figure 21. The cylindrical fibers that compose the mesh (A) can be cut in an oval shape depending on the angle at which the blade encounters the block (B). When the resulting section (C) is placed on a glass slide and stained, the angle between the section and the glass forms a small pocket in which stains can accumulate (D), giving the appearance of “true” staining (E)—that is, of chemical interactions between dyes and their ligands. In reality, this is merely a mechanical entrapment of the staining solution.

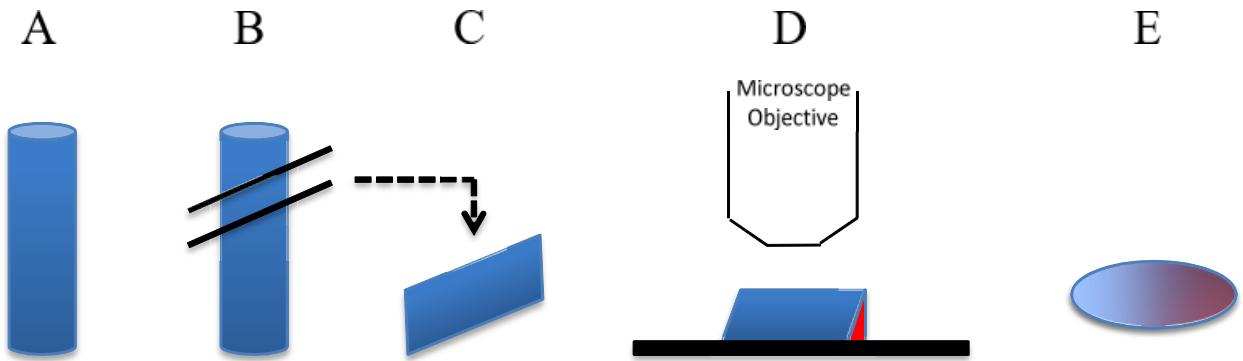


Figure 21. Potential formation mechanism of pooling artifact. A mesh fiber (A) can encounter the microtome blade at an angle (B), forming a section with an angled ledge (C), under which stain can pool (D) and give the appearance of true staining (E).

Stain pooling was observed in several fiber cross sections examined as part of this study. An example of stain pooling, as observed in a pristine TTVT device not expected to stain, is given in Figure 22. Different planes of focus for the fiber cross section are given in Figure 22 that include an image of the plane of the fiber nearest the reader in focus (A) and the plane farther away from the reader, underneath the pristine fiber where the stain is pooled (B).

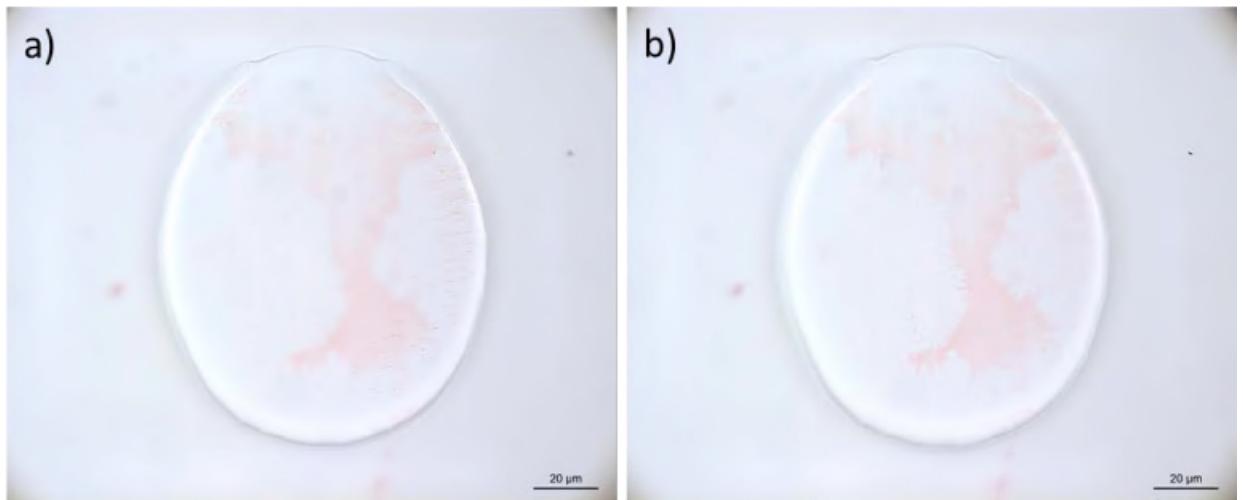


Figure 22. Example of stain pooling is shown. A fiber cross section from a pristine TTVT mesh, not expected to stain, is shown with different planes of focus. For image (a), the plane nearest the reader is in focus. For image (b), the stain pooled underneath the fiber is in focus.

## Polarizing Artifact

Polarized microscopy is a powerful tool in polymer science.<sup>31</sup> With good optics and proper alignment, it allows for the visualization of anisotropic structures, making them appear under varying shades of brightness with a polarizing filter in the microscope's light path.<sup>32</sup> The brightness of the sample when imaged under polarization depends on factors such as sample alignment. The brightness is greatest when the object is aligned at a 45° angle to the polarizers. On the other hand, the object can become difficult to see when aligned parallel to one of the two polarization planes.<sup>33</sup>

The thickness variation resultant from microtomiting, as well as the tendency of an anisotropic fiber to tear away from a surrounding matrix, can create edge artifacts under polarized light. An example of such an artifact is displayed in Figure 23, which is a micrograph of a *nonoxidized* (no possible “bark”) pristine PROLENE mesh fiber subjected to the H&E staining protocol. In Figure 23B and Figure 23C, the fiber is shown under polarized light, and a dark ring of false “bark” is visible on a portion of the fiber exterior. The images in Figure 23 show the same region with and without the polarizer.

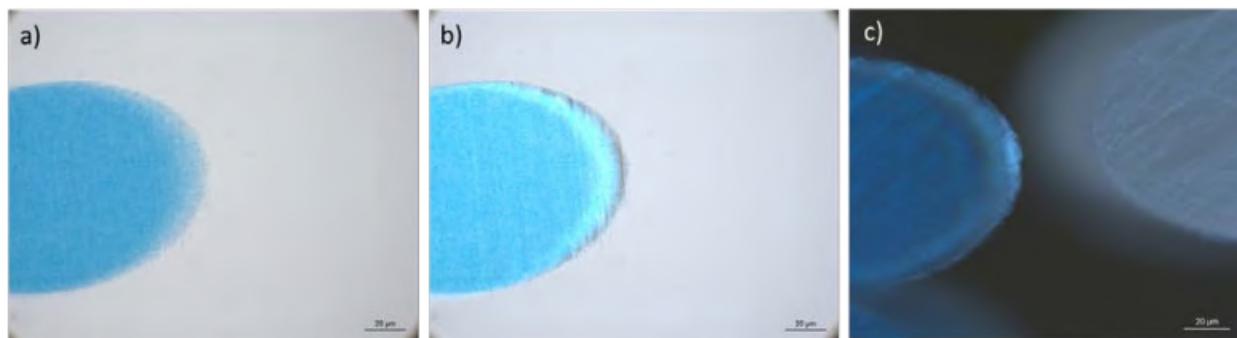


Figure 23. Pristine, nonoxidized PROLENE mesh after staining with H&E. Image (a) was obtained without polarized light. Images (b) and (c) were acquired with polarized light.

<sup>31</sup> Collins, E.A., Bares, J., and Billmeyer, F.W. (1973) Experiments in Polymer Science, John Wiley & Sons.

<sup>32</sup> Wolman, M. (1975). Polarized light microscopy as a tool of diagnostic pathology. *Journal of Histochemistry & Cytochemistry*, 23(1), 21–50.

<sup>33</sup> Ibid.

## Mechanical Behavior of PROLENE Fibers

Dr. Iakovlev opines that oxidation of the PROLENE mesh causes the formation of “a continuous brittle sheath around the mesh filaments contributing to mesh stiffening while the contracting forces acted to deform the mesh. Additionally, degradation of a substance indicates its breakdown into smaller molecules, and in cases of implanted materials, the products of degradation are released into the tissue adding to the complex pathological interactions between the mesh and the human body.”<sup>34</sup> Dr. Iakovlev also notes that his alleged “bark” layer showed large nanocavities (cracks) that indicate brittleness.

From a fundamental polymer science perspective, Dr. Iakovlev’s above-stated opinions are flawed for a number of reasons. First, if we assume, for sake of argument, that the “bark” layer is more stiff than the underlying material, if it is filled with cracks (or nanopores and nanocavities as Dr. Iakovlev calls them), it is by definition discontinuous and therefore mechanically cannot contribute to an increase in stiffening.<sup>35</sup> Dr. Iakovlev cannot have it both ways, either the material is stiff and uniform and leads to mesh stiffening, or it cracks and forms pores and traps dyes; the two are mutually exclusive. Second, if the PROLENE is actually being broken down into smaller molecules, it will tend to become less stiff, not more. Again, Dr. Iakovlev cannot have it both ways (indeed, by stating degradation into smaller molecules leads to stiffening, Dr. Iakovlev underscores the flawed nature of his reasoning).

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<sup>34</sup> Expert report of Dr. Vladimir Iakovlev dated May 23, 2015, p. 54.

<sup>35</sup> Had he chosen to do so, with even a fundamental knowledge of mechanics, Dr. Iakovlev could have easily calculated that a continuous (without his observed pores and cracks) bark of the thickness he has measured could not meaningfully contribute to an increase in mesh stiffness.

## **Conclusion and Opinions**

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Based on my analysis, as well as my education, training and experience in mechanics of materials, polymer science and mechanical engineering, I have formed the following opinions to a reasonable degree of engineering and scientific certainty. If additional information becomes available, I reserve the right to supplement or amend any or all of these opinions.

- Dr. Iakovlev has not used any reliable scientific methods to conclusively determine that an outer oxidized PROLENE layer stains when exposed to H&E. Dr. Iakovlev's assertion that the mesh material has degraded *in vivo* is solely based on visual and microscopic observations of "bark" microcracking. He has conducted no quantitative experiments to confirm his visually based allegation that the mesh material is degraded or oxidized.
- Dr. Iakovlev has not performed any control experiments nor cited any scientific studies that support his belief that degraded PROLENE is capable of being histologically stained with H&E stains, and for these reasons, his conclusions are flawed and suspect.
- Through a series of controlled oxidation, microtoming and microscopy experiments, Exponent demonstrated that oxidized PROLENE mesh fibers and sutures do not become stained with Hematoxylin & Eosin dyes. This fact is supported by polymer science first principles, given that PROLENE does not possess chemical groups amenable to binding with the H&E stain molecules.
- Artifacts can easily be introduced during sample preparation, sectioning, staining, and imaging, giving the appearance of darkened outer layers.
- A brittle outer layer will not contribute to the stiffness of the mesh if it is thin, cracked, and discontinuous. Dr. Iakovlev's opinion that a thin, cracked, porous outer layer causes an increase in mesh stiffness is not consistent with polymer science first principles and contradicted by the measured modulus data from Ethicon's seven year dog study.

If you have any questions or require additional information, please do not hesitate to contact me.



Steven MacLean, Ph.D., P.E.  
Senior Managing Engineer

## **Appendix A: Histology Protocols**

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### **Paraffin-embedded samples**

1. Samples were processed and embedded in an automated tissue processor according to the following schedule:

Processing Step	Incubating Solution	Number of Changes	Duration of Each Incubation Step
1	70% Reagent Alcohol	2	1 hour each
2	80% Reagent Alcohol	1	1 hour
3	95% Reagent Alcohol	1	1 hour
4	100% Reagent Alcohol	3	1.5 hours each
5	Xylene substitute (ProPar, Manufacturer )	3	1.5 hours each
6	Leica EM400 Paraffin wax	2	2 hours each

2. Tissues were embedded in paraffin blocks using Leica EM400 wax
3. The paraffin blocks were trimmed as necessary and cut at 4-6 µm-thick sections
4. The paraffin sections were briefly floated in a water bath set to 40-45°C to remove wrinkles and allow them to flatten
5. The sections were mounted onto adhesive-coated glass slides, then air-dried for 30 minutes and baked in a 45-50°C oven overnight

6. Paraffin-embedded samples were stained by hand using the following protocol:

Processing Step	Incubating Solution	Duration of Each Incubation Step
1	65°C	10 min
2	Xylene	3 min
3	Xylene	2 min
4	Xylene	2 min
5	100% Alcohol	1 min
6	100% Alcohol	1 min
7	95% Alcohol	1 min
8	Water	1 min
9	Harris Hematoxylin	10 min
10	Wash station	1 min
11	Acid Alcohol	30 sec
12	Water	2 min
13	Ammonia Water	1 min
14	Water	1 min
15	Eosin	2 min
16	Water	20 sec
17	100% Alcohol	1 min
18	100% Alcohol	1 min
19	100% Alcohol	1 min
20	Xylene	1 min
21	Xylene	1 min

## Resin-embedded samples

1. Samples were processed and embedded according to the following schedule:

Processing Step	Incubating Solution	Number of Changes	Duration of Each Incubation Step
1	70% Reagent Alcohol	2	1 hour each
2	80% Reagent Alcohol	1	1 hour
3	95% Reagent Alcohol	1	1 hour
4	100% Reagent Alcohol	3	1.5 hours each
5	Technovit 7200	3	3 hours each

2. The resin samples were polymerize using a visible light polymerization unit
3. The blocks were trimmed as necessary, cut using a diamond saw blade, then ground and polished to 10 – 61 µm with a mean thickness of approximately 30 µm.
4. Resin-embedded samples were stained by hand using the following protocol:

Processing Step	Incubating Solution	Duration of Each Incubation Step
1	Water	1 min
2	Harris Hematoxylin	4 hours <sup>36</sup>
3	Water	1 min
4	Acid Alcohol	30 sec
5	Water	1 min
6	Ammonia water	1 min
7	Water	1 min
8	Eosin	1 min
9	Water	30 sec

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<sup>36</sup> The intensity of the stain was monitored microscopically every 15 minutes until the positive control, rabbit skin, was dark enough.

## **Appendix B: Steven MacLean, Ph.D., P.E. CV**

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### **Professional Profile**

Dr. Steven MacLean is a Senior Managing Engineer in Exponent's Polymer Science and Materials Chemistry practice. Dr. MacLean's research and professional interests lie in the area of chemical and physical behavior of polymeric materials in end-use applications. His specialties include part design and analysis, failure analysis, and assessing candidate materials through end-use testing. He has studied various polymer failure mechanisms including stress overload, creep rupture, fatigue, environmental stress cracking, and weathering. Throughout his career he has evaluated the suitability of materials for the automotive, sporting goods, medical, business equipment, and construction industries. Dr. MacLean is proficient in a variety of analytical techniques including finite element analysis, statistical methods, as well as empirical approaches to long-term reliability and durability.

Dr. MacLean has considerable practical experience in the conversion of raw materials into finished goods. Throughout his career, he has worked with polymer conversion processes such as injection molding, compression molding, blow molding, extrusion, thermoforming, and laminating. In addition, he has worked on numerous projects involving common secondary operations used throughout the plastics industry such as metallic plating, adhesive joining, painting, as well as vibration and ultrasonic welding.

Dr. MacLean is well versed in voluntary standards and national regulations and codes that often prescribe the technical performance of plastic materials in various industries. Standards organizations and regulatory bodies with which he has interacted include Underwriters Laboratories (UL), International Electrotechnical Commission (IEC), US EPA, California Air Resource Board, NSF International, and ASTM International. He has also participated in numerous sustainability and life cycle assessments (LCAs) per ISO 14040 standards to quantify the environmental impact of manufactured products and raw materials.

Prior to joining Exponent, Dr. MacLean spent 16 years in the plastics industry at General Electric Plastics and SABIC Innovative Plastics where he held several technical positions of

increasing responsibility. His activities included material selection and testing for high-demand applications, product safety assessments, failure analysis, and intellectual property analysis.

## **Academic Credentials and Professional Honors**

Ph.D., Materials Science, University of Rochester, 2007

M.S., Materials Science and Engineering, Rochester Institute of Technology, 2001

M.E., Mechanical Engineering, Rensselaer Polytechnic Institute, 1997

B.S., Mechanical Engineering, Rensselaer Polytechnic Institute (with honors), 1993

Tau Beta Pi; Pi Tau Sigma; Society of Plastics Engineers ANTEC Best Paper Award

## **Licenses and Certifications**

Registered Professional Engineer, New York, #16-079001

Registered Professional Engineer, Maryland, #41593

National Council of Examiners for Engineering and Surveying, Record #47204

Certified Six Sigma Black Belt

## **Publications**

MacLean SB, et al. Fractographic examination and tensile property evaluation of 3D printed acrylonitrile butadiene styrene (ABS). Proceedings, ANTEC, 2015.

MacLean SB, et al. Fractographic examination of failures in polycarbonate and polyoxymethylene due to impact, tensile, fatigue and creep mechanisms. Proceedings, ANTEC, 2013.

MacLean SB, et al. Comparison of mass transit material flammability requirements and trends for aircraft and train applications in Europe and North America. Proceedings, ANTEC, 2012.

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MacLean SB, et al. Root cause investigation of cracked polycarbonate blender jars. Proceedings, ANTEC, 2010.

MacLean SB. Plastics, electronics and the environment: How new global regulations affect material choices. Kunststoffe International 2008 Sept; 97–100.

MacLean SB. Plastics, electronics and the environment: How new global regulations affect material choices. Telepati Aylık Telekom 2008 Mar; 74–77.

MacLean SB, et al. Monolayer barrier for small engine fuel tanks. Plastics Technology Online 2007 June.

MacLean SB. Environmental effects of poly(phenylene ether) blends due to long-term exposure to potable hot water. Ph.D. Dissertation, University of Rochester, 2007.

MacLean SB, et al. The effects of recycling and heat history for select high polymers. Proceedings, ANTEC 2001.

MacLean SB, et al. Poly(phenylene ether) engineering thermoplastic provides creep resistance, toughness and fire resistance required for high performance pallets. Proceedings, ANTEC 2000.

## **Presentations**

MacLean SB, Moll J. The importance of polymer structure-property relationships in preventing failure in medical devices. Medical Grade Polymers Conference, Woburn, MA, 2015.

MacLean SB. Fundamentals of plastics fractography. ANTEC, Cincinnati, OH, 2013.

MacLean SB. Challenges associated with replacing metal with plastic. Material Science and Technology Conference, Pittsburgh, PA, 2012.

MacLean SB, et al. Fractography of unfilled thermoplastic materials subjected to common mechanical failure modes. Material Science and Technology Conference, Pittsburgh, PA, 2012.

MacLean SB. Common analytical techniques for failure analysis – A Resin Manufacturer's Perspective. ANTEC, Boston, MA, 2011.

MacLean SB, et al. Plastic failure analysis and prevention expert panel. ANTEC, Boston, MA, 2011.

MacLean SB. Root cause investigation of cracked polycarbonate blender jars. ANTEC, Orlando, FL, 2010.

MacLean SB. Diffusion of potable hot water in poly(phenylene ether) blends. American Chemical Society Conference, Binghamton, NY, 2006.

MacLean SB. Changes in polycarbonate and ABS mechanical properties due to multiple heat histories. Society of Plastics Engineers ANTEC, Dallas, TX, 2001 (with Korzen).

MacLean SB. Yield Improvement for gas assist panels using statistical methods. Society for the Plastics Industry Conference, Vancouver, BC, 2000.

MacLean SB. Design methodologies for metal to plastic conversion. General Electric Plastics Innovation Seminar, Columbus OH, 2000.

MacLean SB. Fundamentals of polymer science. General Electric Plastics Customer Design Workshop, Pittsfield, MA, 1998, 1999.

MacLean SB. Designing for injection molded parts. General Electric Plastics Customer Design Workshop, Pittsfield, MA, 1998, 1999.

MacLean SB. Mechanical behavior of polymeric materials. General Electric Plastics Engineering Workshop, Pittsfield, MA, 1997.

## **Prior Experience**

Director, Global Agency Relations & Product Safety, SABIC Innovative Plastics,

2007-2011

Global Technical Manager, General Electric Plastics, 2003–2007

Six Sigma Black Belt, General Electric Plastics, 2001–2003

Senior Application Development Engineer, General Electric Plastics, 1998–2001

Plastic Design and Analysis Leader, General Electric Plastics, 1996–1998

Edison Engineer, Lockheed Martin Corporation, (Formerly General Electric Aerospace),

1994–1996

## **Professional Affiliations**

Society of Plastics Engineers (Senior Member)

SPE Failure Analysis & Prevention Group – Board Member and Treasurer

ASTM D20 Plastics Committee Member

## **Appendix C: Testimony of Steven MacLean, Ph.D., P.E.**

**Workhorse Custom Chassis, LLC v. Robert Bosch LLC** (Marion Superior Court of Indiana), October 2012 (Deposition)

**Trice, et al. v. Toyota Motor Corporation, et al.** (United States District Court – District of Minnesota), August 2013 (Deposition), January 2015 (Trial)

**Alberto, et al. v. Toyota Motor Corporation, et al.** (Genesee County, Michigan), November 2013 (Deposition)

**Metropolitan Property & Casualty Insurance v. LG Electronics, et al.** (United States District Court – District of Arizona), August 2014 (Deposition)

**Nease v. Ford Motor Company** (United States District Court of West Virginia - Huntington Division), December 2014 (Deposition), March 2015 (Trial)

**Wubker, et al. v. A&A Manufacturing Company, et al.** (Santa Fe County, New Mexico), January 2015 (Deposition)

**Promethean Insulation Technology LLC v. Reflectix, Inc., et al.** (United States District Court of Eastern Texas - Marshall Division), June 2015 (Deposition), October 2015 (Trial)

**Nettleton, et al. v. Ford Motor Company** (United States District Court Northern District of California - San Francisco Division), July 2015 (Deposition)

**Mullins, et al. v. Ethicon** (United States District Court Southern District of West Virginia - Charleston Division), September 2015 (Deposition)

**Hower v. Excel Industries, Inc., et al.** (United States District Court Western District of Missouri - Southern Division), November 2015 (Deposition)

**Brunswick Woodworking Company, Inc. et al. v. Slocum Adhesives Corp., et al.,** (Circuit Court for Montgomery County, Maryland) January 2016 (Deposition)

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## Production Materials

[DEPO.ETH.MESH.00006437-39]

[DEPO.ETH.MESH.00006440-42]

[DEPO.ETH.MESH.00006443-45]

[DEPO.ETH.MESH.00006446-49]

[DEPO.ETH.MESH.00006450-52]

[DEPO.ETH.MESH.00006453-55]

[DEPO.ETH.MESH.00006456-58]

[DEPO.ETH.MESH.00006459-61]

[DEPO.ETH.MESH.00006462-64]

[DEPO.ETH.MESH.00006465-67]

[DEPO.ETH.MESH.00006468-70]

[DEPO.ETH.MESH.00006471-73]

[DEPO.ETH.MESH.00006474-76]

[DEPO.ETH.MESH.00006477-79]

[ETH.MESH.04091125-26]

[ETH.MESH.06195201-05]

[ETH.MESH.09269739-40]

[ETH.MESH.09273600-01]

[ETH.MESH.12009027-35]

[ETH.MESH.15406846-999]

[ETH.MESH.15955438-73]

Gynecare Instructions Eth.Mesh.03427878

10/0 Prolene explanted after 4½ years in eye (Ref. Ethicon Notebook 1962/73) Project 47201 [ETH.MESH.15958495-8502]

10/0 Prolene suture removed from patients eye after 4½ years (Product Management) Project 47201 [ETH.MESH.15958512-8517] [ETH.MESH.15958518-8523]

10-0 Prolene suture removed from patient's eye after 4½ years, Dr. Drews (Ethicon, Inc. Analytical Chemistry Department) Project 47201 [ETH.MESH.15958524]

25 2-24512 fourier transform-infrared examination of prolene microcrack and photo-oxidized polypropylene

[DEPO.ETH.MESH.00006304-06]

Bry Prolene Explants, Dr. S. Garg Pr. # 16102 [ETH.MESH.15958470-8477]

China Mesh EGS-August 2009 Update [ETH.MESH.10492861-63]

Clinical Expert Report: Prolene Polypropylene Mesh [ETH.MESH.03712324-44]

Completion Report: Design Verification for Soft Prolene Mesh/ Mesh Curling [ETH.MESH.02182839-44]

Cracks in lens surface near haptic, Christine Jordan PR. #41001 [ETH.MESH.15958492-8494]

ERF 82-147 Microscopic Examination of Prolene (polypropylene) suture and dacron graft returned for norfolk surgical group, ltd (human Retrieval) [DEPO.ETH.MESH.00006307-08]

ERF 83-352 Human retrieval samples from Dr. Gregory, Norfolk Surgical Group [DEPO.ETH.MESH.00006309]

ERF 84-533 PROLENE 7 Year Explant [DEPO.ETH.MESH.00006310-  
DEPO.ETH.MESH.00006311]

ERF 84-533 prolene polypropylene suture explant from Dr. Drewes  
[DEPO.ETH.MESH.00006312]

Examination of 5 0 and 6 0 Cardiovascular PROLENE Suture Explanted after 2 to 6 years implantation [DEPO.ETH.MESH.00006313-15]

Examination of Ends of PREP and Prolene Sutures Reported to Have Broken in Animals [ETH.MESH.15958433-8444]

Examination of Ends of PREP and PROLENE Sutures Reported to Have Broken in animals.pdf [DEPO.ETH.MESH.00006316-24]

Expert Report of Howard Jordi w/ exhibits from a NJ case dated 5.20.14 (under New Jersey cases expert reports)

Expert Report of Vladimir Iakovlev (Richard Schmidt)

Explanted after 2 to 6 years. Nine samples were submitted by Research Foundation through Dr. Lunn. The results were provided in the memo. (DX25875)

FDA Reclassification of Prolene Sutures (1990) (ETH.MESH.10665538)

Figures included in seven year report (dog studies) [ETH.MESH.11336505-6525]

Handwritten Notes for project 16102 re: Measurement of cracks in explanted Prolene sutures. Investigator E. Lindemann [DEPO.ETH.MESH00004769-4772]

Handwritten notes for Project No. 45702 (May go with DEPO.ETH.MESH00004761 as it indicates "cont.p.99) "Development of procedure to \_\_\_\_ cracks in \_\_\_\_ explanted suture." Investigator E. Lindemann [DEPO.ETH.MESH00004768]

Handwritten notes for project no. 45702 re: Development of procedure to \_\_\_\_ \_\_\_\_ \_\_\_\_ of cracks in Prolene Suture." Appears to describe method and result from examination of sutures. Investigator E. Lindemann [DEPO.ETH.MESH00004761-4766]

Handwritten notes from Dan Burkley lab notebook regarding Gudoin prolene explants (September 22, 1987) (DEPO.ETH.MESH.000000367 - 368)

Handwritten notes regarding completion and conclusion from the investigation/examination of 23 Prolene sutures. Second page is dated 02/01/1988 but appears to go with document. Investigator: not legible [DEPO.ETH.MESH00004757-4758]

Intra ocular lens, C. Jordan PR. #41001 [ETH.MESH.15958481-8485]

Intraocular lenses, C. Jordan PR. #41001 [ETH.MESH.15958486-8491]

John Karl's January 23, 2003 Memo titled Prolene Resin Manufacturing Specifications and Additive Package (ETH.MESH.02268619)

July 6, 2007 email from Dr. Engel re "How inert is polypropylene?" (ETH.MESH.05447475)

June 15, 1982 memo from Anthony Lunn regarding Crack Depth in Explanted Prolene Polypropylene Sutures (ETH.MESH.12831405-406)

Laboratory Notebook of D. Burkley covering March 20, 1984 to October 23, 1984 [DEPO.ETH.MESH00000347 -375]

Ledger and attached slides [ETH.MESH15406846-6977]

Listing of explants, SEM evaluation and SEM number with attached slides containing handwritten information. [ETH.MESH.15406978-6999]

March 12, 2012 Memo re Response to email from Clare Huntington 26 January 2012 regarding publication by Clavé et al., "Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants" (ETH.MESH.07226481)

Meeting Minutes: TVT Development-Team-Meeting 7.28.1999 [ETH.MESH.08165497-99]

Memo Burkley to A.J. Melveger re: IR Microscopy of Explanted Prolene Received from Prof. R. Guiddin [ETH.MESH 12831391-1404]

Memo by Matlaga, Sheffield & Fetter to P. Marshall re: Human Retrieval Specimens from Dr. Roger Gregory, Norfolk Surgical Group. Samples were submitted from evaluation. The results are included in the memo. [ETH.MESH.1595440-5442]

Memo Dr. Borysko to Melveger et al. re: Examination of 5/0 and 6/0 Cardiovascular Prolene Sutures [ETH.MESH15958410-8432]

Memo Frick to Matlage enclosing specimens of graft and suture material from two of Dr. Roger Gregory's patients. [ETH.MESH15955443-5452]

Memo from Burkley to J. McDivitt re: Fourier Transform-Infrared Examination of Prolene Microcrack and Photo-Oxidized Polypropylene [ETH.MESH15958336-8395]

Memo Garfield Jones to E.A. Block re: Prolene Polypropylene Suture/Tissue Specimens. Enclosing Prolene suture explants received from Dr. Margaret Billingham with attached letter regarding the sutures. [ETH.MESH 15955472-5473]

Memo Lunn to Melveger re: Crack Depth in Explanted Prolene Polypropylene Sutures [ETH.Mesh 12831405-1407]

Memo Matlaga and Sheffield to Dr. R.L. Kronenthal re: Examination of Prolene (Polypropylene) Sutures from Human Cardiovascular Explants received from Dr. Margaret Bellingham for evaluation. The results are included in the memo. [ETH.MESH15955462-5468]

Memo Matlaga to Dr. A. Lunn re: Prolene (Polypropylene) Microcracks. Matalaga reviewed histological preparation from past samples more critically and provided the results. [ETH.MESH15955438-5439]

Memo Matlaga to P. Marshall re: Human Retrieval Samples [ETH.MESH15958400-8404]

Memo Matlaga to R.L. Kronenthal re: Prolene Polypropylene Suture Explant from Dr. Drewes [ETH.MESH15958405-8407]

Memo Moy to A. Melveger re: Prolene Microcrack Experiments [ETH.MESH 15958445-8451]

Memo Moy to A.J. Melveger re: Prolene Microcracking [ETH.MESH15958452-8469]

Memo R.J. Reinhardt to Dr. D.C. Marshall re: Prolene Polypropylene Suture. Included was a dissected surgical specimen of a graft sutured with Prolene suture received from Dr. Richard J. Sanders of Denver, Colorado. [ETH.MESH15955469-5471]

Memo Schiller to T. Davidson et al. re: Polene 7 year explant ERF Accession #84-533 [ETH.MESH15958408-8409]

Memo to Dr. A. Melveger re: Optical examination of 7 /12 year Prolene Explant, ERF Acc. #84-194. Examination results included along with Handwritten notes Microscopic Examination of Prolene (Polypropylene) Suture and Dacron Graft Returned for Norfolk Surgical Group, LTD (Human Retrieval) (ERF Accession No. 82-147) [ETH.MESH.15958396-8399]

Page from Prolene IFU re: Degradation

Project No 47201 (16 - 1983.05.25 - ETH.Mesh.15958400-8404)

Prolene – 7 year Explant from Dr. Drews (ERF Acc. #84-533) [ETH.MESH.15958503-8507]

Prolene Microcrack Experiments.pdf [DEPO.ETH.MESH.00006325-31]

prolene microcracking [DEPO.ETH.MESH.00006386]

Prolene Package Insert re: Degradation (ETH.MESH.09634318)

Prolene Suture (treated and un-treated) (Dr. Guidain) [ETH.MESH.15958478-8480]

Quebec Explants - SEM Evaluation [DEPO.ETH.MESH.00004755]

Risk Assessment Summary for Product in the Gynecare TVT Secure System  
[ETH.MESH.11353422-39]

Satya Garg's November 12,1987 Memo regarding Gudooin prolene explants Study Meeting Minutes 10/8/87 (ETH.MESH.12831407)

Second Iolab job – requested by Sal Romano Project #45702-509 [ETH.MESH.15958510-8511]

SEM 10551-10572 83D057-83D960-83D035-84D007-84D010-83D067-83TM020  
[DEPO.ETH.MESH.00006332-39]

SEM 1205-1208 and 1211-1212 and 1215-1216 PROLENE - tissue digestion treatment  
[DEPO.ETH.MESH.00006340-41]

SEM 4088-4101 Intra-ocular Lens for SR29477 [DEPO.ETH.MESH.00006342-46]

SEM 4102-4117 Intra-ocular Lens for SR29477 [DEPO.ETH.MESH.00006347-52]

SEM 4749-4754 Intra-ocular Lens cracks near haptic for SR29477  
[DEPO.ETH.MESH.00006353-55]

SEM 5627-5641 10-0 PROLENE explants [DEPO.ETH.MESH.00006356-63]

SEM 7467-7478 7 year explant ERF 84-533 [DEPO.ETH.MESH.00006364-68]

SEM Negatives 4696-4701 Intra-ocular Lens [DEPO.ETH.MESH.00006369-70]

SEM Negatives 4736-4741 Intra-ocular Lens [DEPO.ETH.MESH.00006371-72]

SEM Negatives 5627-5641 10-0 PROLENE Explants [DEPO.ETH.MESH.00006373-78]

SEM Negatives 5627-5641 10-0 PROLENE Explants [DEPO.ETH.MESH.00006379-84]

Seven Year Dog Study (Lewis trial exhibit no. 1291) (Complete)

Seven Year Dog Study (Used as exhibit at the 30(b)(6) deposition of Thomas Barbolt [ETH.MESH.11336184 - ]

SR14154 10-0 PROLENE explant [DEPO.ETH.MESH.00006385]

Sunoco MSDS (ETH.MESH.02026591)

The Use of Mesh in Hernia Repair by L. Thomas Divilio, MD, FACS [ETH.MESH.14442958-76]

Third type sample from Iolab Corp., Intra-Ocular Lens Project #47416 [ETH.MESH.15958508-8509]

NDA – 4.16.1969 PROLENE FDA Approval (ETH.MESH.09625731-09625737)

PROLENE suture NDA Preclinical Studies.pdf (ETH.MESH.09626242 – 09626359)

1973 Rabbit Study for PROLENE Mesh.pdf (ETH.MESH.10575607 – 10575613)

PSE 97-0197.pdf (ETH.MESH.05315240 – 05315295)

Eth Mesh 04384112 – Biocompatibility Risk Assessment for the TVT-L Device – June 6 2001.pdf (ETH.MESH.04384112 – 04284125)

Crack Depth in Explanted PROLENE Polypropylene Sutures memo (ETH.MESH.123831405 – 123831406)

Human Retrieval Specimens from Dr. Roger Gregory, Norfolk Surgical Group memo1983.03.29 (ETH.MESH.15955440-15955442)

Ethicon's Seven Year Dog Study ETH.MESH.09888187

Ethicon's Seven Year Dog Study ETH.MESH.09888189

Ethicon's Seven Year Dog Study ETH.MESH.09888218-222

Ethicon's Seven Year Dog Study ETH.MESH.09888188

Ethicon's Seven Year Dog Study ETH.MESH.11336183

Ethicon's Seven Year Dog Study ETH.MESH.11336181

Ethicon's Seven Year Dog Study ETH.MESH.11336081-082

Ethicon's Seven Year Dog Study ETH.MESH.11336166-168

Ethicon's Seven Year Dog Study ETH.MESH.09888191

Tensile Strength Study of Colorless and Pigmented Monofilament Polypropylene Sutures in the Rat (ETH.MESH.09626336 - 09626345)

Histological Evaluation and Comparison of Mechanical Pull Out Strength of Prolene Mesh and Prolene Soft Mesh in a Rabbit Model (EHT.MESH.10039989 - 10040024)

Monofilament Prolene In Vivo Breaking Strength Loss (ETH.MESH.10575510)

Prolene Polypropylene Sutures: Breaking Strength of Prolene Sutures After Subcutaneous Implantation in Rats (ETH.MESH.10575614)

Non-Absorbable Sutures; In Vivo Tensile Strength Values of Production Non-Absorbable Sutures Tested To Supply Reference Tensile Strength Values (ETH.MESH.10665625 - 10665661)

NDA - Approved Labeling - Prolene Sutures - 1969 (ETH.MESH.09629447 - 09629448)

NDA - FDA Prolene NDA Supplement with Transitory Language (ETH.MESH.09630649)

NDA - Librojo Affidavit

NDA - Prolene NDA - Insert Changes Approvals

NDA - Prolene NDA with Blue Composition (ETH.MESH.09625606 - 09625632)

Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device 8-8-1997 (ETH.MESH.00349228 - 00349237)

## Bellew Case Materials

### Expert Reports

Ducheyne, Paul

Iakovlev, Vladimir

Jordi, Howard

Klinge, Uwe

Muehl, Thomas

Thames, Shelby

### **Depositions**

Iakovlev, Vladamir [8.12.2014] (Corbett)

Jordi, Howard C., MD [8.19.2014]

Thames, Shelby F., Ph.D. [9.4.2014]

### **Trial**

Iakovlev, Vladimir [03.05.2015]

### **Miscellaneous**

All FTIR spectra (Four charts dated 6/17/2014)

Invoice #9475 from Jordi Labs to Anderson Law offices

Invoice #9685 from Jordi Labs to Anderson Law offices

NIST Polystyrene Standard (dated 6/18/2014)

Ong, Kevin SEM Images

### **Huskey Case Materials**

#### **Depositions**

Iakovlev, Vladamir [3.18.2014] (Huskey-Edwards)

Trial Transcript (Guelcher Testimony) w/ Exhibits [8.25.2014]

Trial Transcript (Thames Testimony) w/ Exhibits [9.2.2014]

## **Expert Reports**

Dunn, Russell (Huskey-Edwards)

Dunn, Russell (Rebuttal) (Huskey-Edwards)

Guelcher, Scott (Huskey-Edwards)

Guelcher, Scott (Rebuttal)

Guelcher, Scott (2nd Supplimental) (Huskey-Edwards)

Ong, Kevin (Huskey-Edwards)

Pandit, Abhay (Huskey-Edwards)

Thames, Shelby (Huskey-Edwards)

## **Miscellaneous**

Plaintiff's slides used with Guelcher

## **Lewis Case Materials**

### **Expert Reports**

Jordi, Howard

Jordi, Howard (Rebuttal)

Ong, Kevin

Thames, Shelby

Guelcher, Scott (Rebuttal)

## **TVT NJ Case Materials**

### **Expert Reports**

Ducheyne, Paul

Elliott, Daniel

Iakovlev, Vladimir

Jordi, Howard

Klinge, Uwe

Muehl, Thomas

Rosenzweig, Bruce

Pence, Peggy

### **Carlino Case Materials**

Dr. Iakovlev's Expert Report 8-28-15

Civil Action Complaint – Short Form

Ethicon's Response to Request for Production 8-24-15

### **McGee Case Materials**

Dr. Klinge's Expert Report 10-13-13

11.9.15 (TVM) McGee - letter to counsel enclosing plaintiff expert reports

Complaint and Jury Demand (J&J McGee, Kathryn)\_18144909\_1

### **Wave 1 Case Materials**

#### **Expert Reports**

Jordi, Howard (Wave 1, Lewis, Bellew)

Guelcher, Scott

Guelcher, Scott (corrected)

Klinge, Uwe (SUI, POP)

Mays, Jimmy

Priddy, Duane

Ostergard, Donald

Iakovlev, Vladimir (General)

Iakovlev, Vladimir (Adams, Beach, Bennett, Boggs, Daino, Destefano-Raston, Dimock, Fox, Frye (original), Frye (supplemental), Funderburke, Georgilakis, Hankins, Hooper, Hoy, Justus, Kaiser, Kropf, Loustaunau, Massey, McBrayer, Nix, Phelps, Ruebel, Ruiz, Smith, Smith, Stone, Stubblefield, Taylor, Teasley, Vignos-Ware, White, Wolfe, Wroble)

Muehl, Thomas

## **Depositions**

Priddy, Duane (3-8-2016)

Mays, Jimmy (3-2-16)

## **Other Materials**

Mpathy Medical Devices, Ltd. Minimesh® polypropylene mesh. 510(k) #K041632

Sofradim Production. ParieteneTM Duo Polypropylene mesh and ParieteneTM Quadra Polypropylene mesh. 510(k) #K072951

Coloplast A/S. RestorelleTM polypropylene mesh. 510(k) #K103568

C.R. Bard, Inc. Bard® InnerLaceTM BioUrethral Support System. 510(k) #K031295

C.R. Bard, Inc. Avaulta™ Solo Support System and Avaulta™ Plus Biosynthetic Support System. 510(k) #K063712

American Medical Systems. BioArc TOTM Subfascial Hammock. 510(k) #K040538

American Medical Systems. AMS Large Pore Polypropylene mesh. 510(k) #K033636

MentorCorp. Mentor ObTapeTM Trans-obdurator Surgical Kit. 510(k) #042851

MLE, Inc. Suture Fixation Device. 510(k) #K021834

Boston Scientific Corp. Pinnacle Pelvic Floor Repair Kit II. 510(k) #081048

Boston Scientific Corp. Pinnacle Lite Pelvic Floor Repair Kit. 510(k) #122459

Island Biosurgical, Inc. Island Biosurgical Bolster. 510(k) #K960101

Ethicon, Inc. Modified PROLENE Polypropylene Mesh Nonabsorbable Synthetic Surgical Mesh. 510(k) #962530

Ethicon, Inc. Gynemesh PROLENE Soft (Polypropylene) Mesh. 510(k) # K013718

ATR – Theory and Applications.pdf Pike Technologies

EAG FTIR Technique Note

Education Guide: Special Stains and H&E Second Edition, Editors: George L. Kumar and John A. Kiernan., 2010 Dako North America, Carpinteria, California

Myers, R. (2011). The Basic Chemistry of Hematoxylin. Available from:  
<http://www.leicabiosystems.com/pathologyleaders/the-basic-chemistry-of-hematoxylin/>

TVT Classic 510(K) (ETH.MESH.08476210 - 08476342)

ISO\_10993\_Testing

ASTM D3895

Trial Testimony of Vladimir Iakovlev (Cardenas) 8.18.2014

Trial Transcript of Eghnayem v. Boston Scientific 11.6.2014

Iakovlev, Vladimir Expert Report of (Iholts)

Iakovlev FULL REPORT ETH MDL Consolidated Case -8-24-15

Jordi FULL REPORT ETH MDL Consolidated Case 8-24-15

Guelcher FULL REPORT ETH MDL Consolidated Case 8-24-15

Klinge ETH MDL Consolidated Case-Expert Report 8-24-15

Muhl ETH MDL Consolidated Case-Expert Report-8-24-15

Iakovlev, Vladimir Expert Report - Clowe

Thames, Shelby Expert Report – Contrell

Thames, Shelby Trial Tesimony - Batiste

Barbolt 30(b)(6) deposition exhibit--list of studies 1-8-14

Scott, Guelcher Trial Testimony and Exhibits - Perry

Barbolt New Jersey Cases deposition 9-9-2012

Barbolt New Jersey Cases deposition day II 9-10-2012

Barbolt Pelvic Repair System Products Liability Litigation deposition 8-14-2013

Barbolt Pelvic Repair System Products Liability Litigation deposition day II 8-14-2013

Barbolt Pelvic Repair System Products Liability Litigation deposition 1-7-2014

Barbolt Pelvic Repair System Products Liability Litigation deposition day II 1-7-2014

Rosenzweig, Bruce Final Cantrel report 6-6-14

Rosenzweig, Bruce Final Corbet Report

Burkley, Dan deposition day 1, dated 5-22-2013

Burkley, Dan deposition day 2, dated 5-23-2013

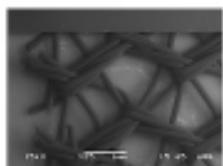
## **Appendix E: Compensation**

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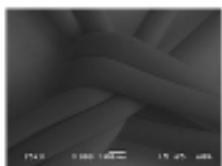
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## **Appendix F: Study Images**

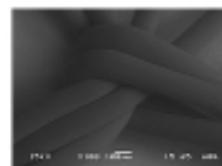
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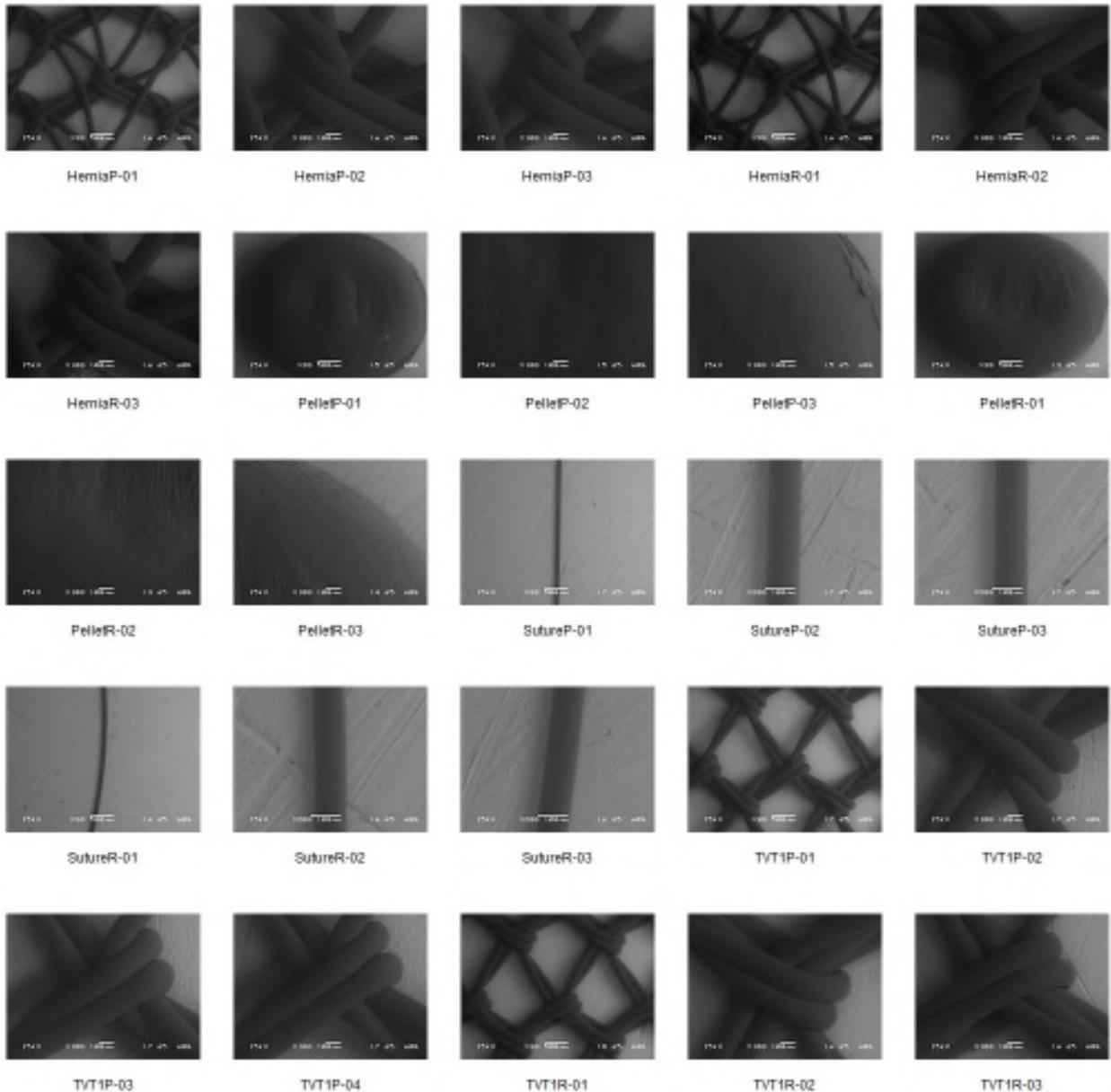
HemiaNetHR\_01

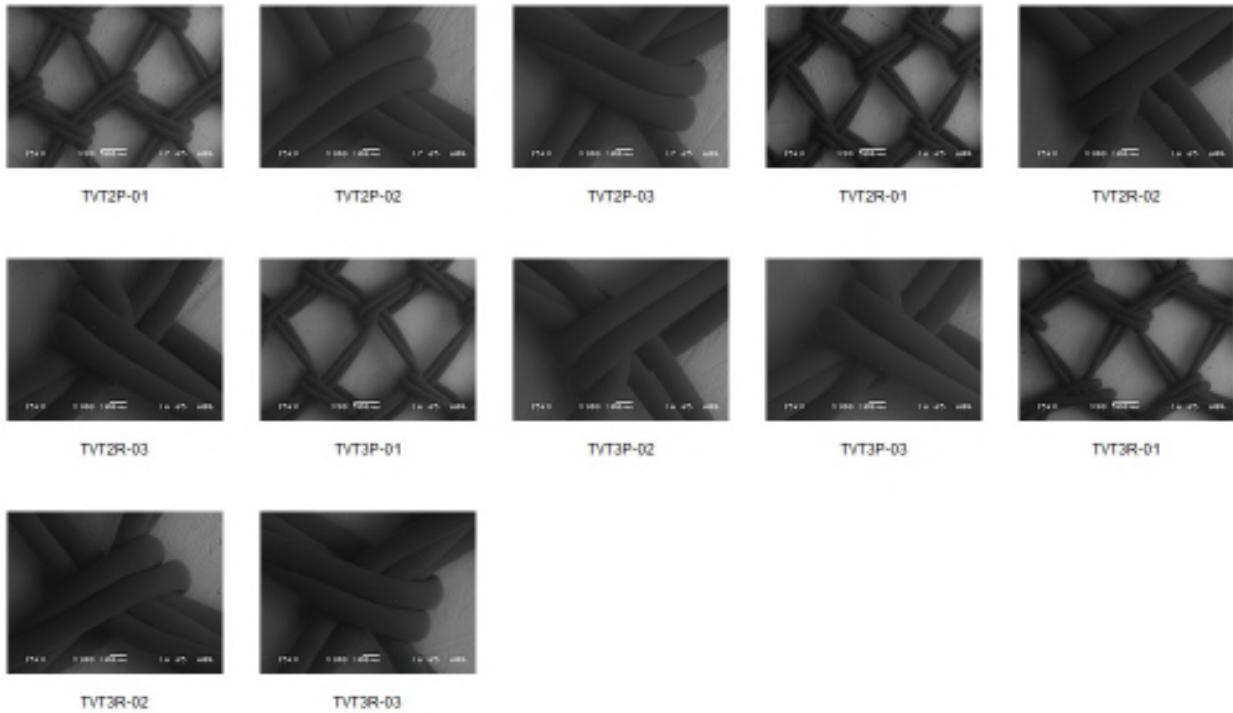


HemiaNetHR\_02



HemiaNetHR\_03







DSC\_5380



DSC\_5381



DSC\_5388



DSC\_5389



DSC\_5398



DSC\_5399



DSC\_5410



DSC\_5411



DSC\_5421



DSC\_5422



DSC\_5423



DSC\_5432



DSC\_5433



DSC\_5384



DSC\_5385



DSC\_5402



DSC\_5403



DSC\_5414



DSC\_5415



DSC\_5426



DSC\_5427



DSC\_5436



DSC\_5437



DSC\_5443



DSC\_5444



DSC\_5473



DSC\_5474



DSC\_5475



DSC\_5386



DSC\_5387



DSC\_5404



DSC\_5405



DSC\_5416



DSC\_5417



DSC\_5428



DSC\_5429



DSC\_5438



DSC\_5439



DSC\_5445



DSC\_5446



DSC\_5382



DSC\_5383



DSC\_5400



DSC\_5401



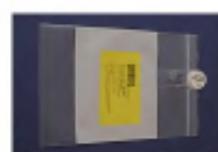
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DSC\_5413



DSC\_5424



DSC\_5425



DSC\_5434



DSC\_5435



DSC\_5441



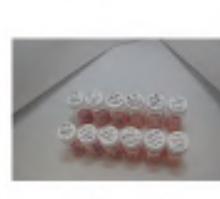
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DSC\_5462



DSC\_5463



DSC\_5464



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DSC\_5466



DSC\_5467



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DSC\_5470



DSC\_5471



DSC\_5476



DSC\_5477



DSC\_5478



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DSC\_5488



DSC\_5489



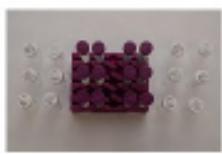
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DSC\_5493



DSC\_5494



DSC\_5495



DSC\_5496



DSC\_5497



DSC\_5498



DSC\_5499



DSC\_5500



DSC\_5501



DSC\_5502



DSC\_5503



DSC\_5504



DSC\_5505



DSC\_5506



DSC\_5507



DSC\_5508



DSC\_5509



DSC\_5510



DSC\_5511



DSC\_5512



DSC\_5513



DSC\_5514



DSC\_5515



DSC\_5516



DSC\_5517



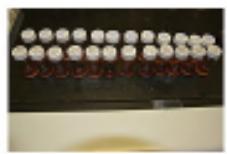
DSC\_5518



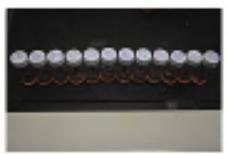
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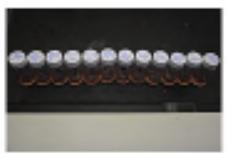
DSC\_7024



DSC\_7025



DSC\_7026



DSC\_7027



DSC\_7028



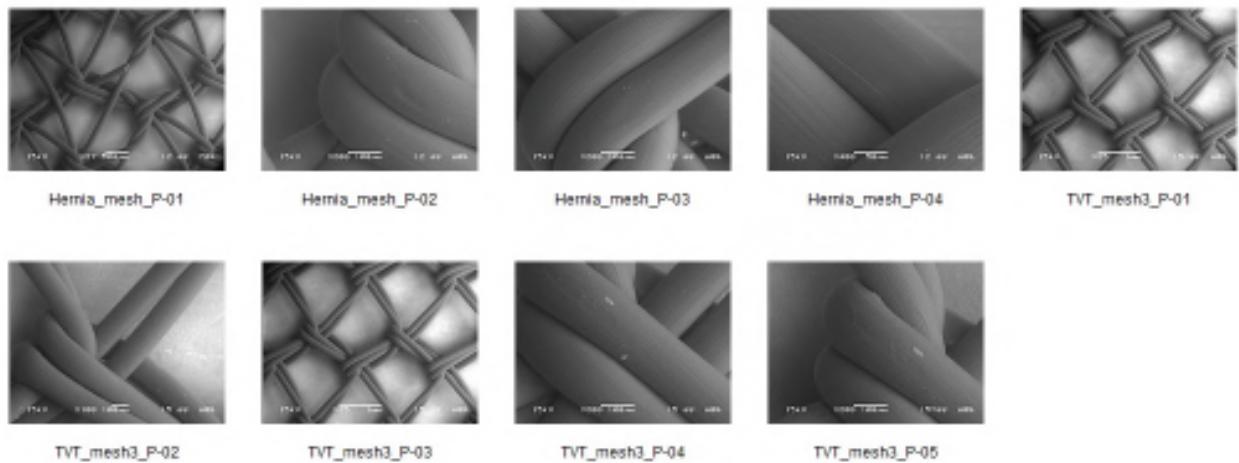
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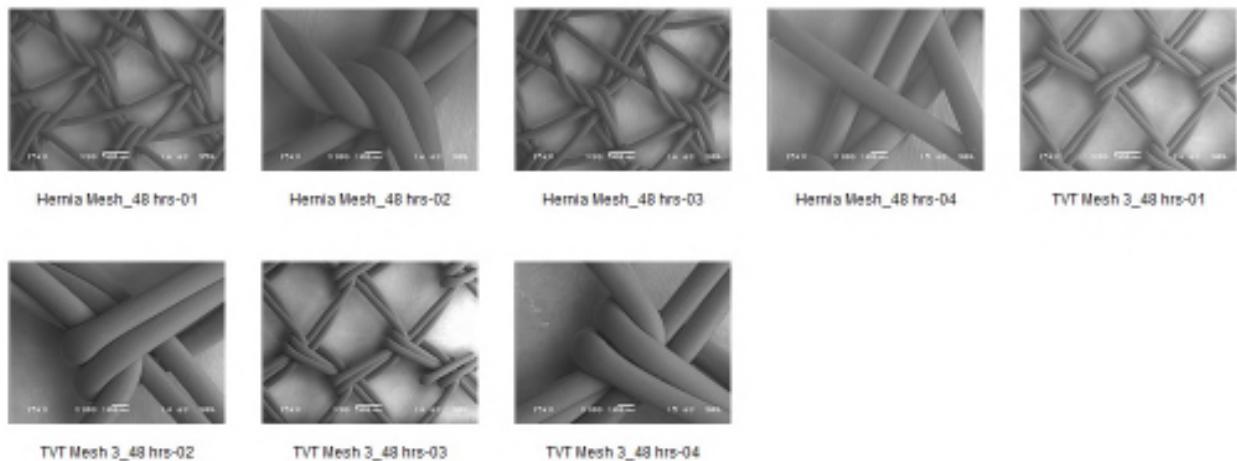


DSC\_7030



DSC\_7031









IMG\_2077



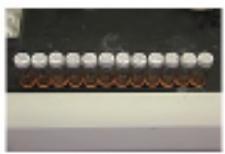
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IMG\_2079



IMG\_2080



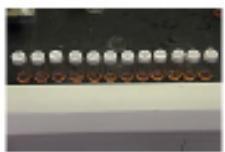
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IMG\_2082



IMG\_2083



IMG\_2084



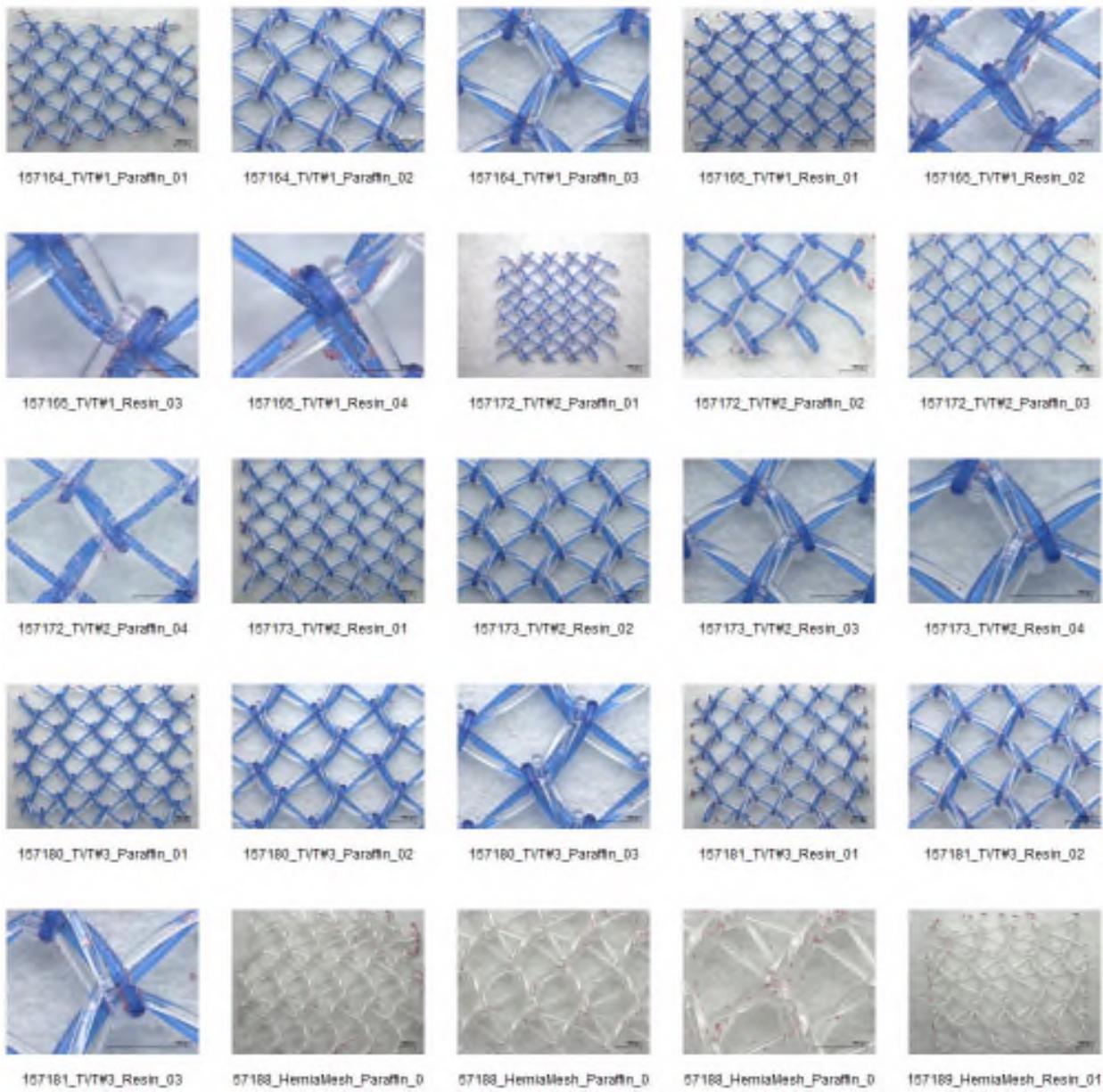
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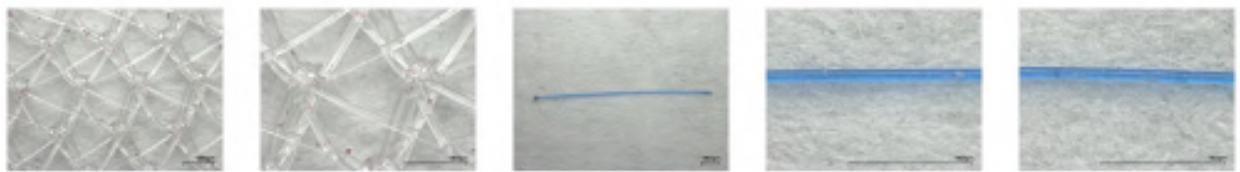


IMG\_2086



IMG\_2087





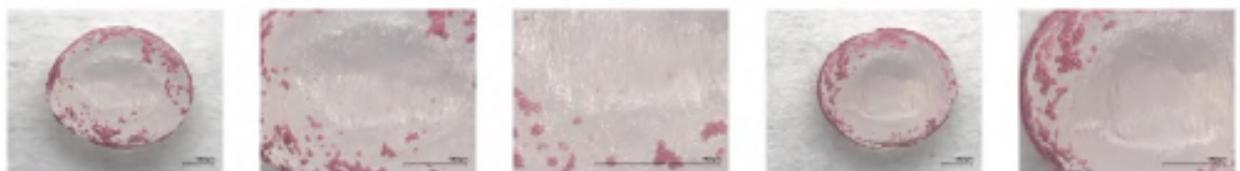
157188\_HemiaMesh\_Resin\_02

157188\_HemiaMesh\_Resin\_03

57196\_Suture\_Paraffin-Resin\_C

57196\_Suture\_Paraffin-Resin\_C

57196\_Suture\_Paraffin-Resin\_C



157232\_pellet\_Paraffin\_01

157232\_pellet\_Paraffin\_02

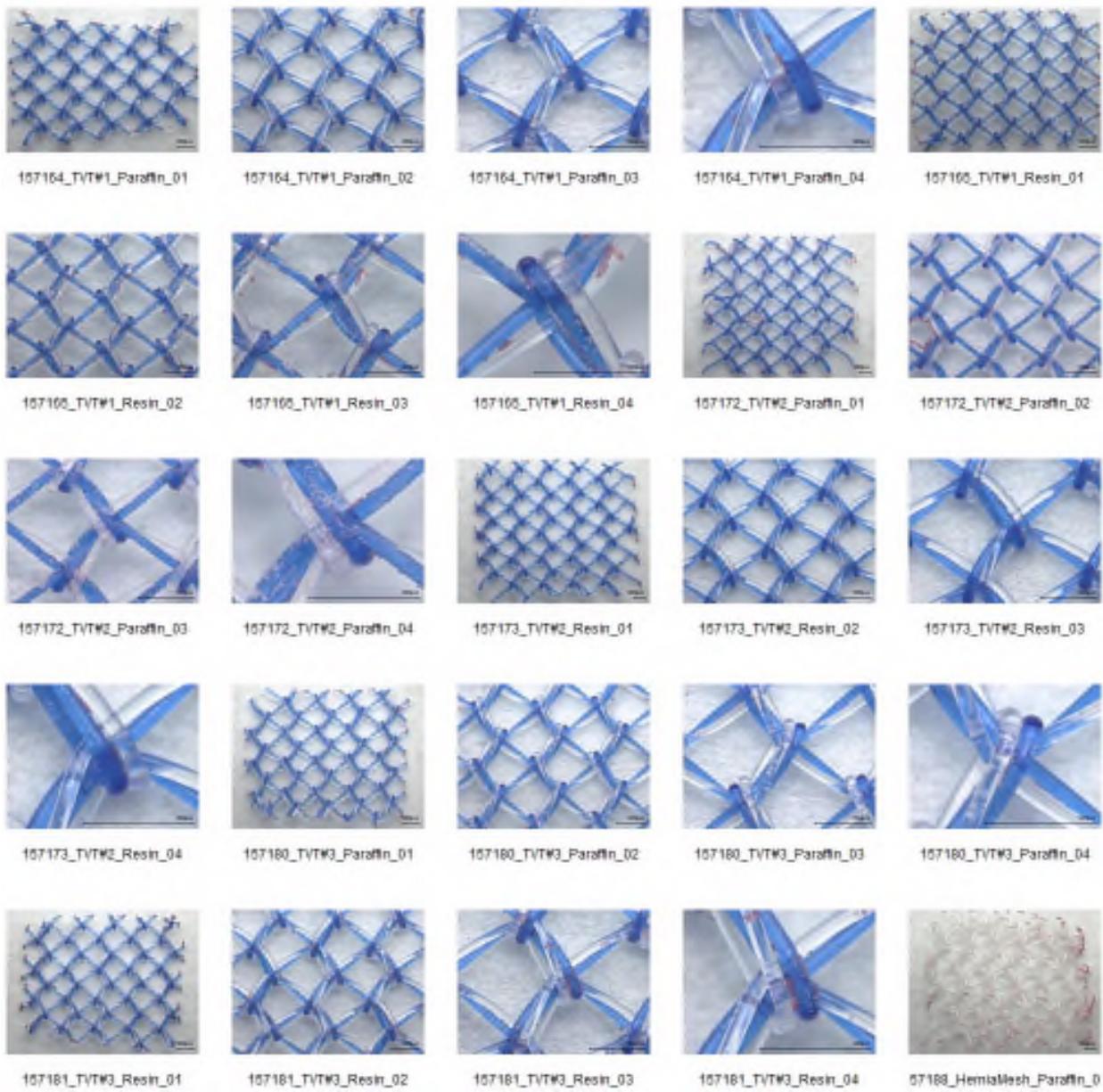
157232\_pellet\_Paraffin\_03

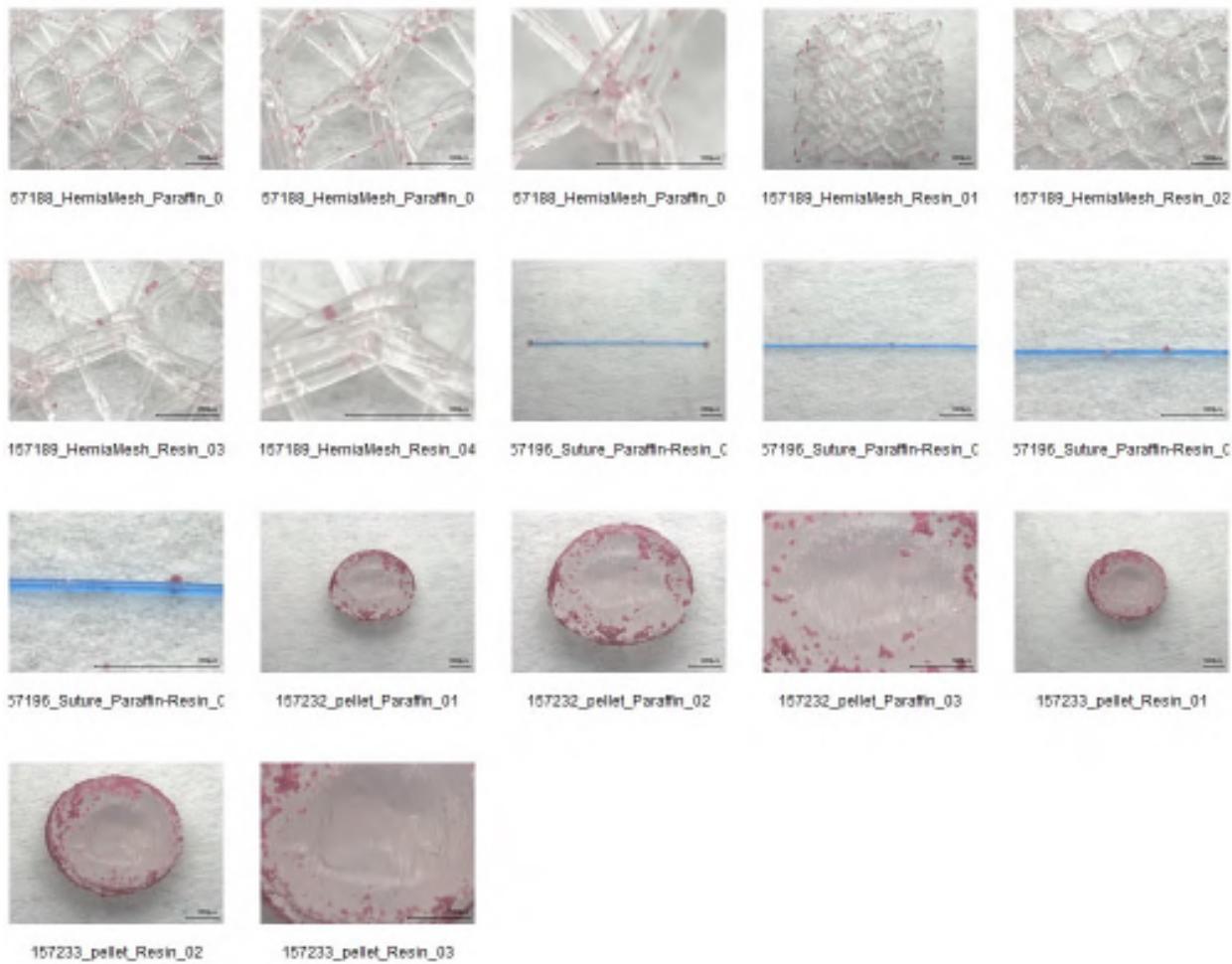
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157233\_pellet\_Resin\_02



157233\_pellet\_Resin\_03



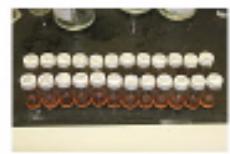




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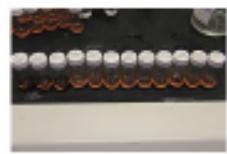
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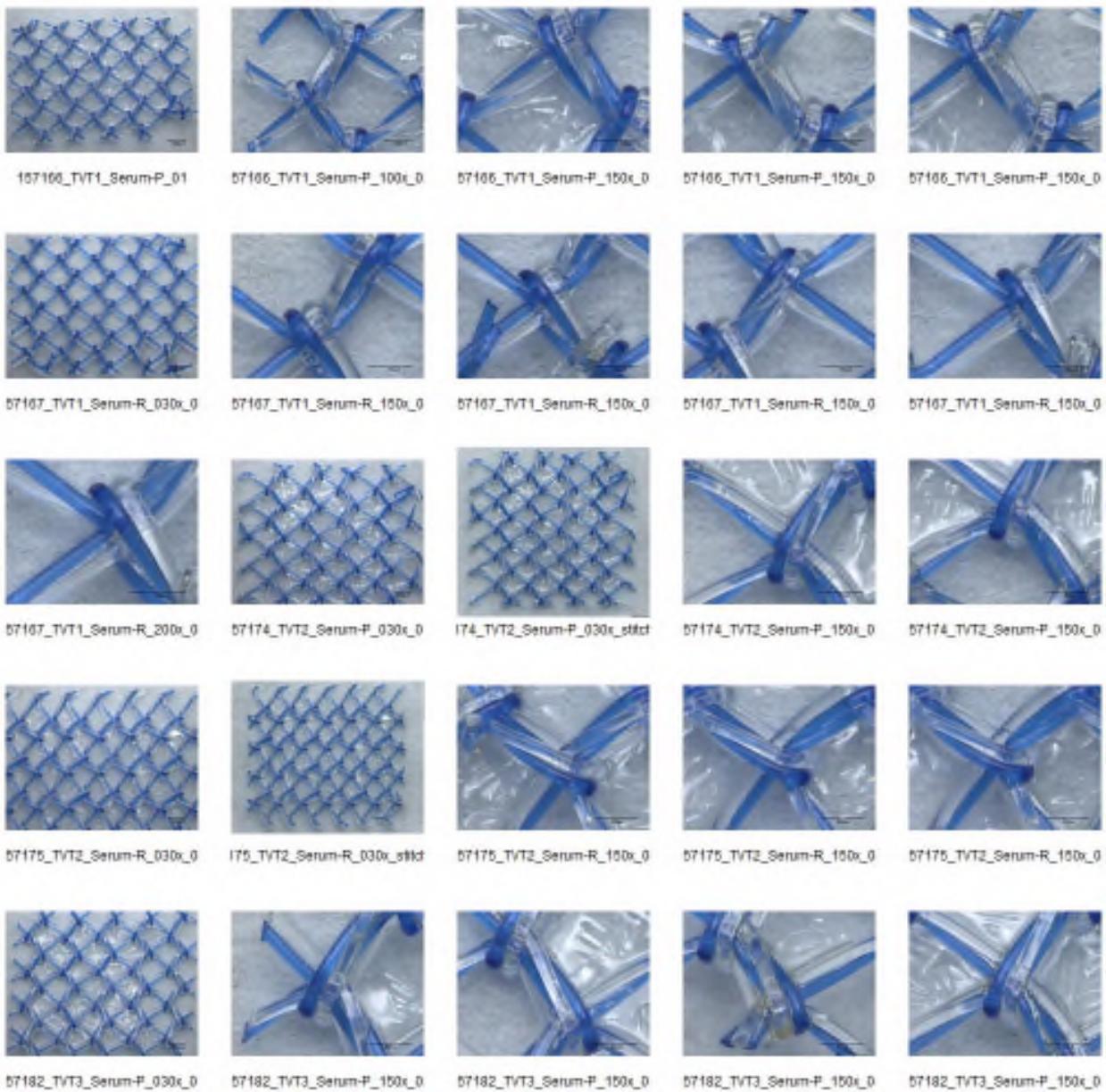
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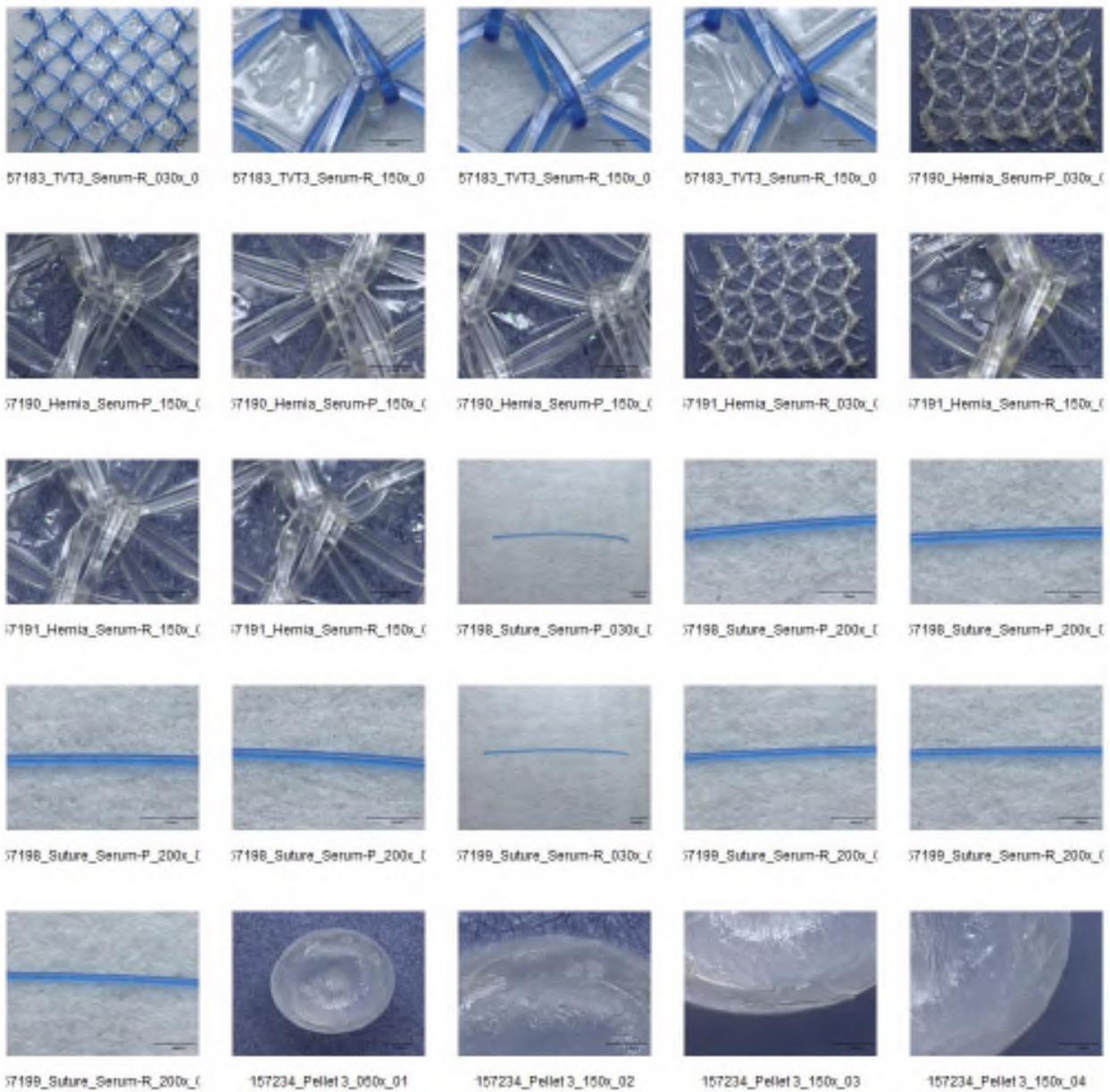


IMG\_2157



IMG\_2158







157235\_Pellet 4\_050x\_01



157235\_Pellet 4\_150x\_02



157235\_Pellet 4\_150x\_03



IMG\_1022



IMG\_1023



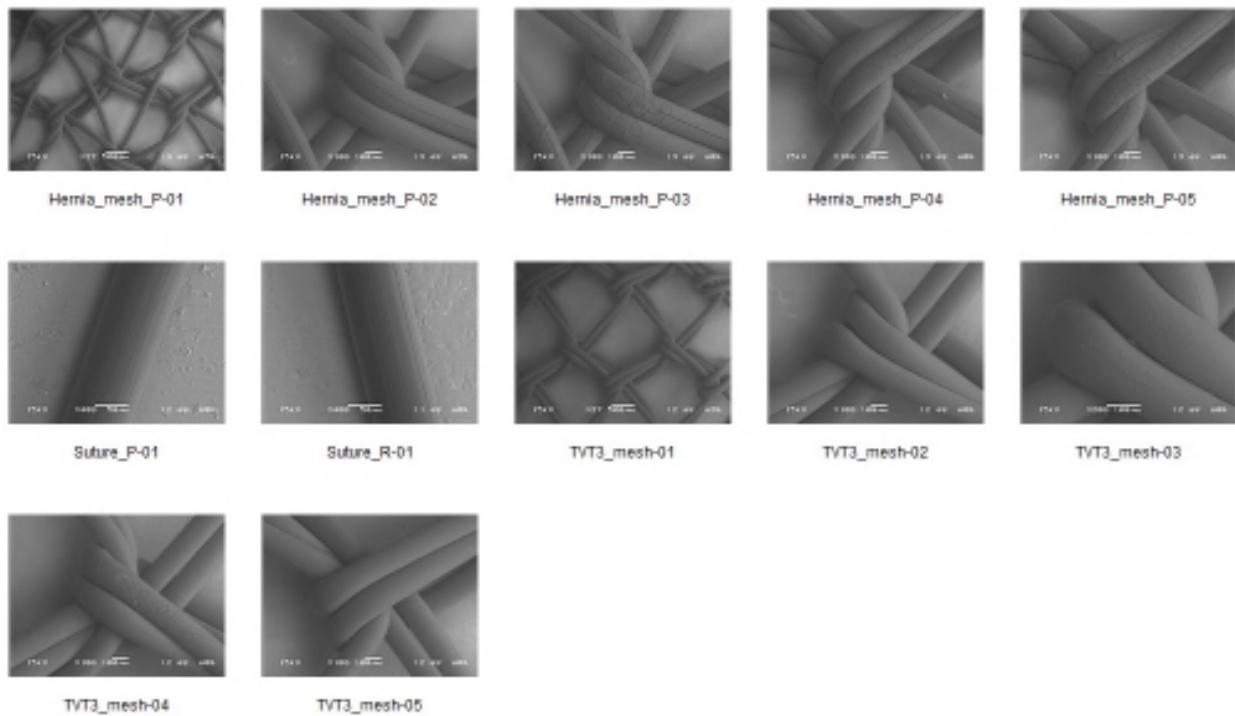
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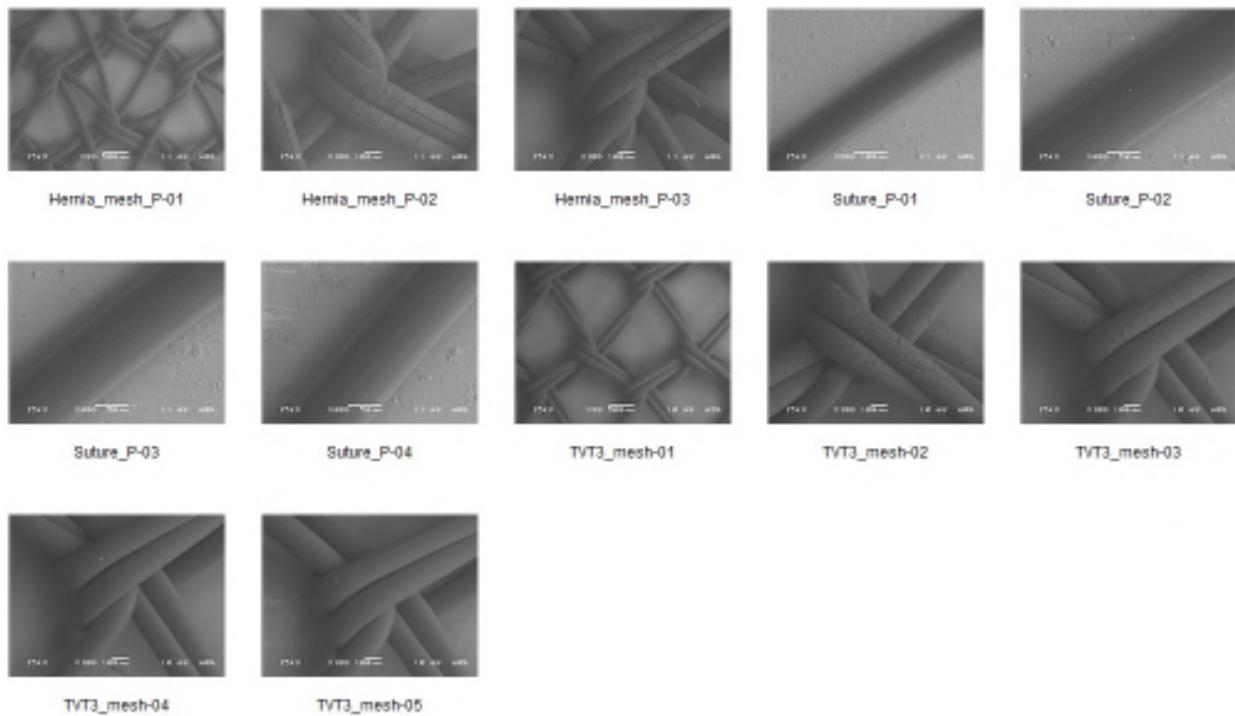


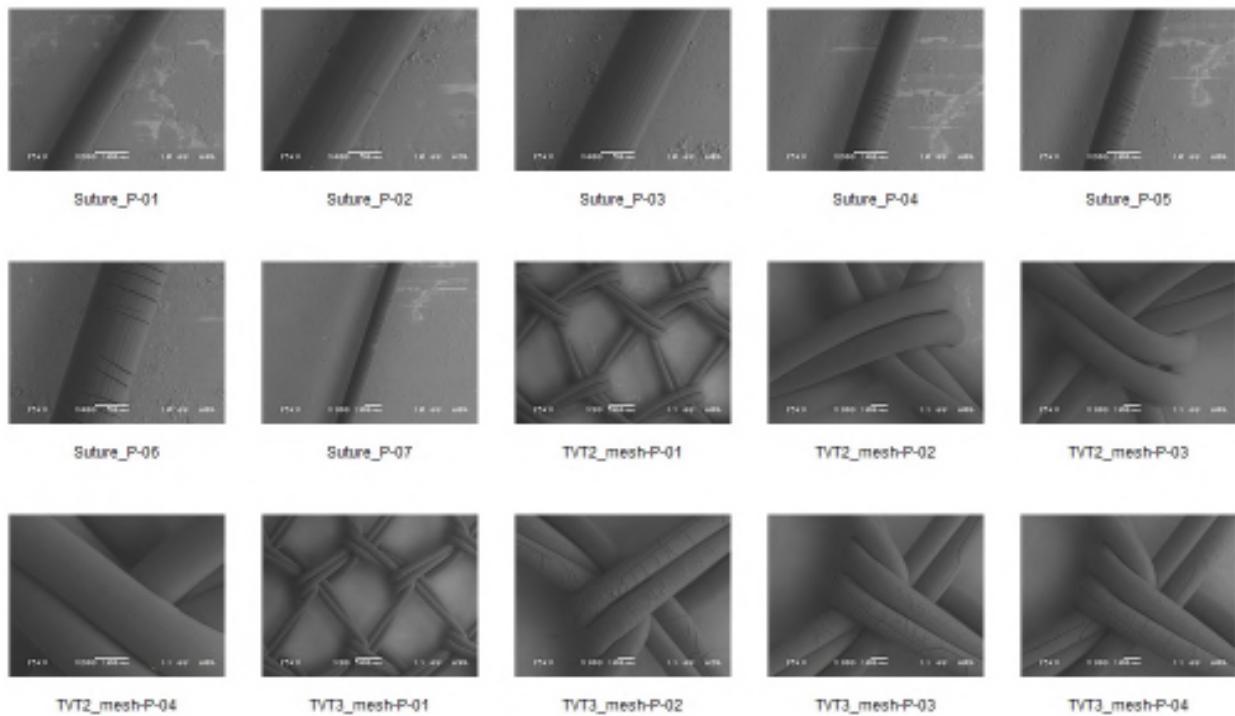
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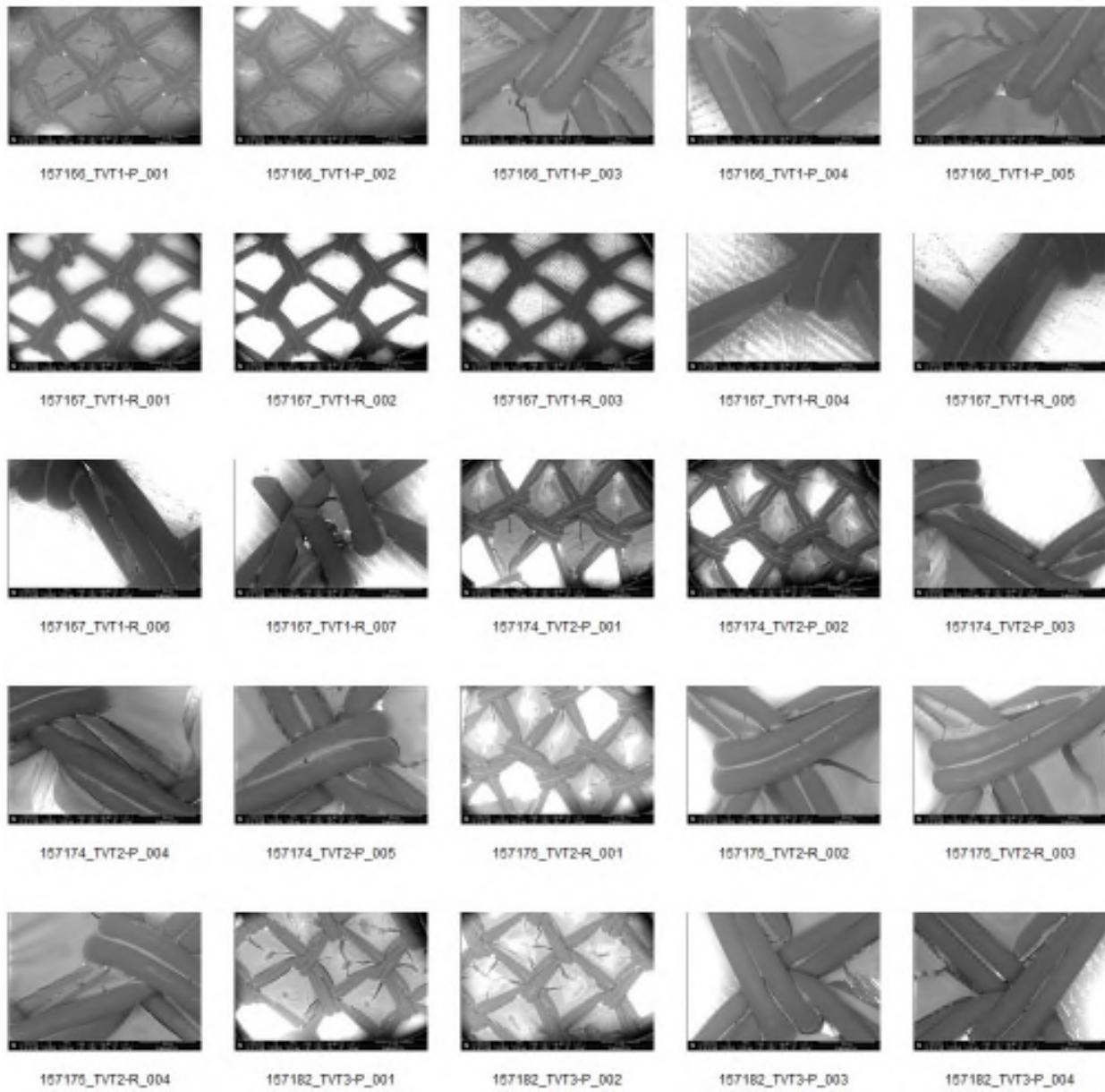


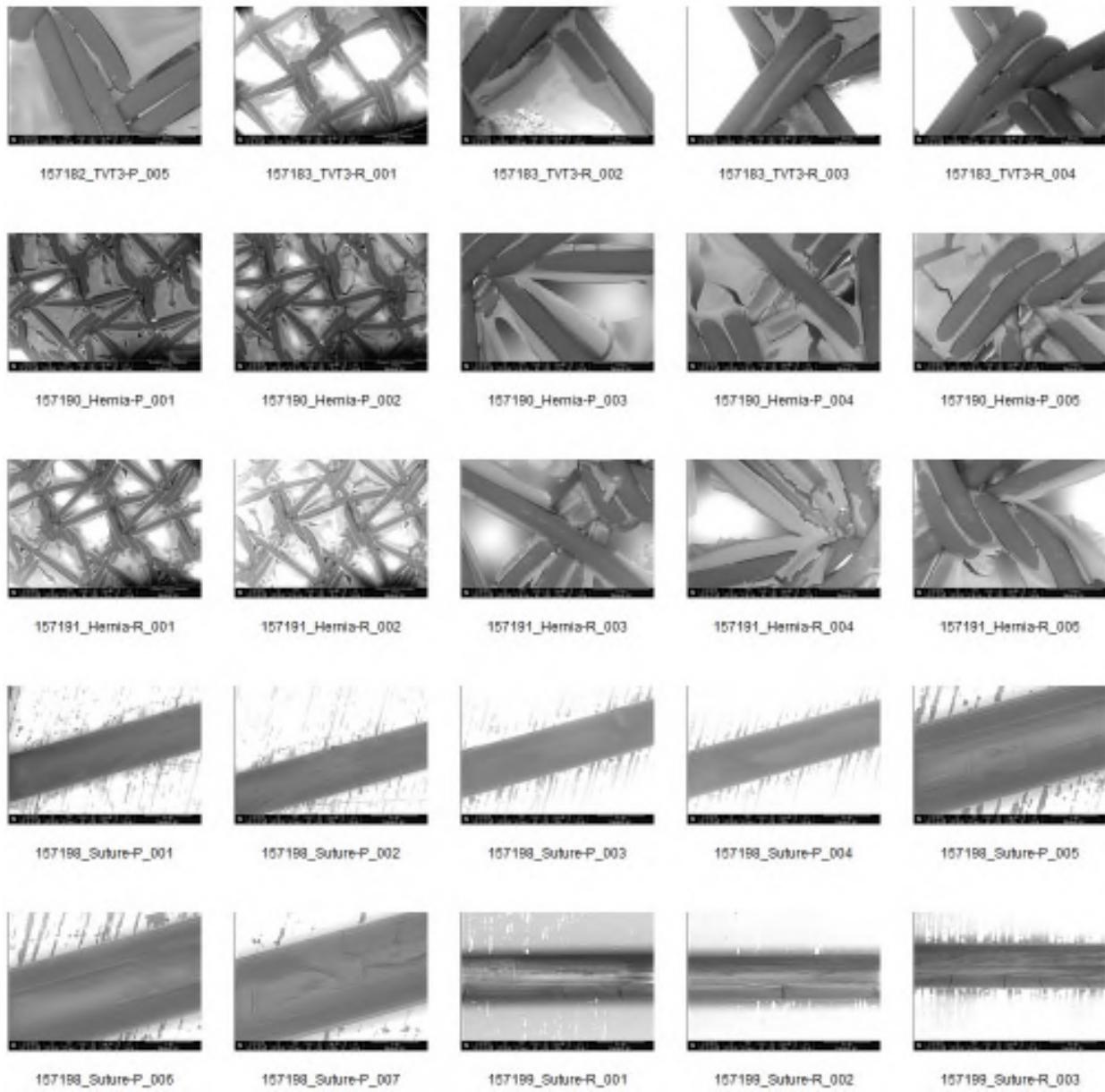
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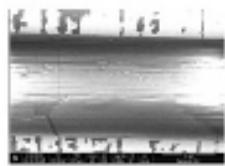




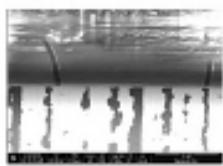




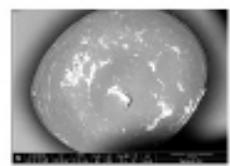




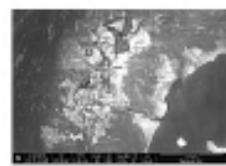
157199\_Suture-R\_004



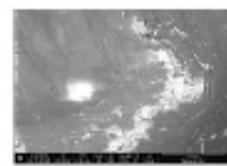
157199\_Suture-R\_005



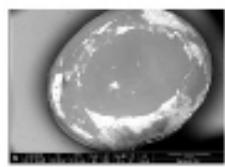
157234\_Pellet3\_001



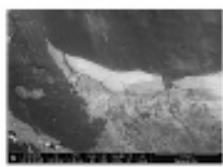
157234\_Pellet3\_002



157234\_Pellet3\_003



157235\_Pellet4\_001



157235\_Pellet4\_002



157235\_Pellet4\_003



DSC\_7052



DSC\_7053



DSC\_7054



DSC\_7055



DSC\_7056



DSC\_7057



DSC\_7058



DSC\_7059



IMG\_1008



IMG\_1009



IMG\_1010



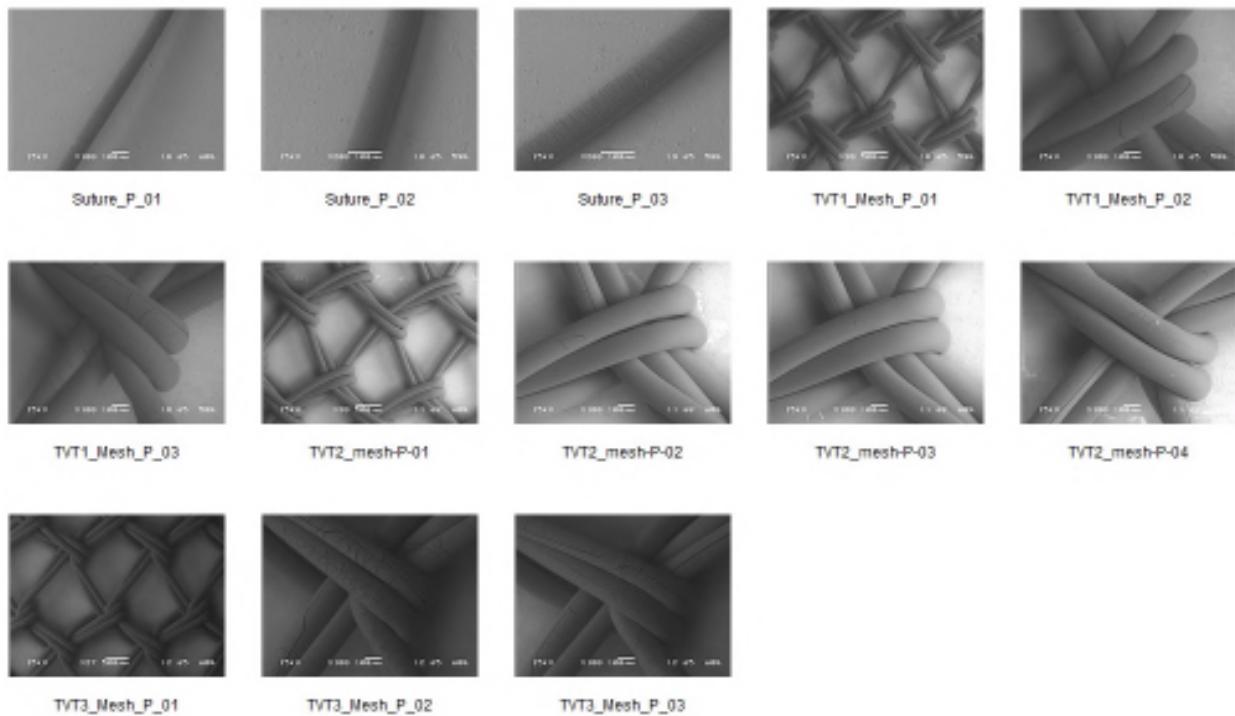
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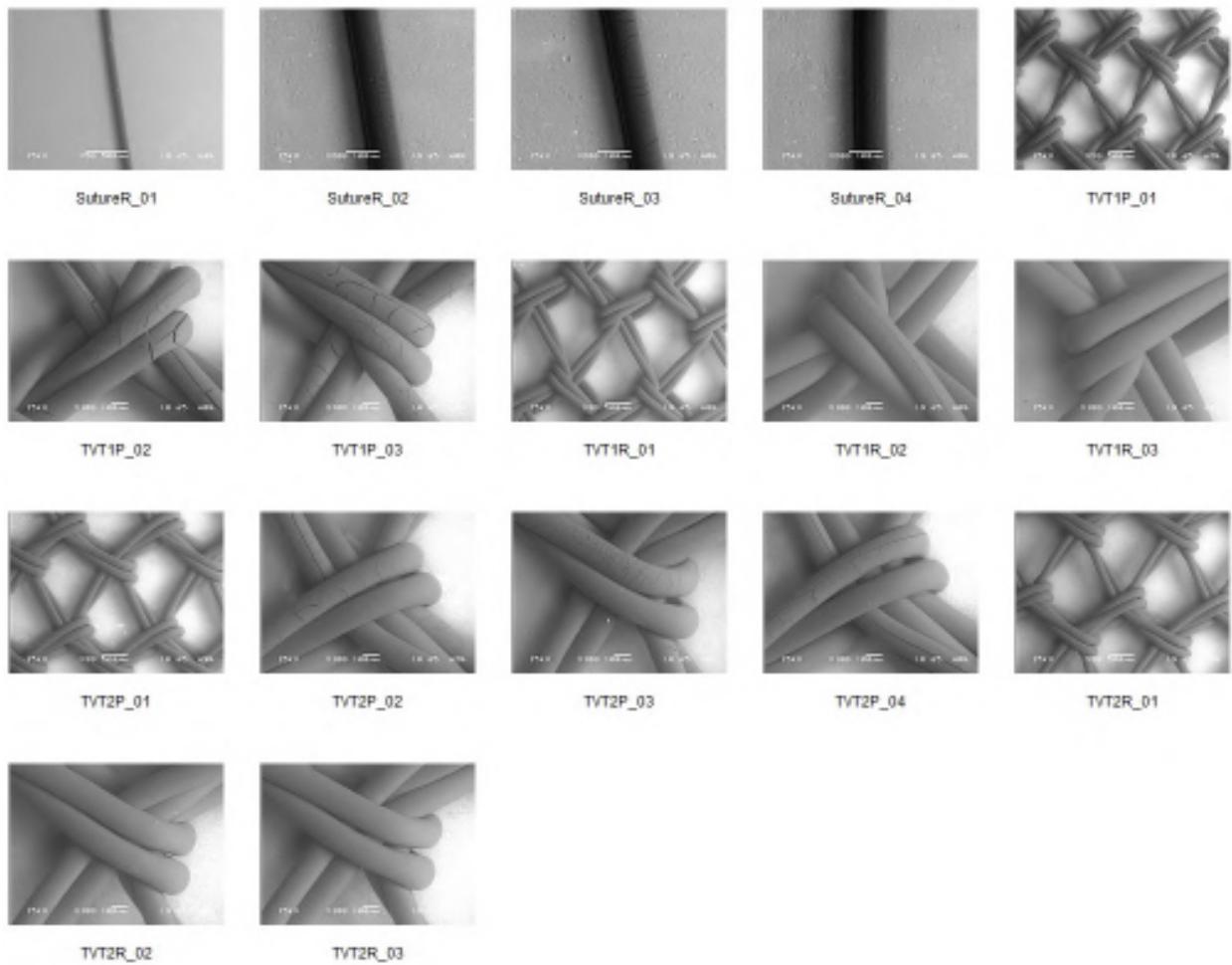


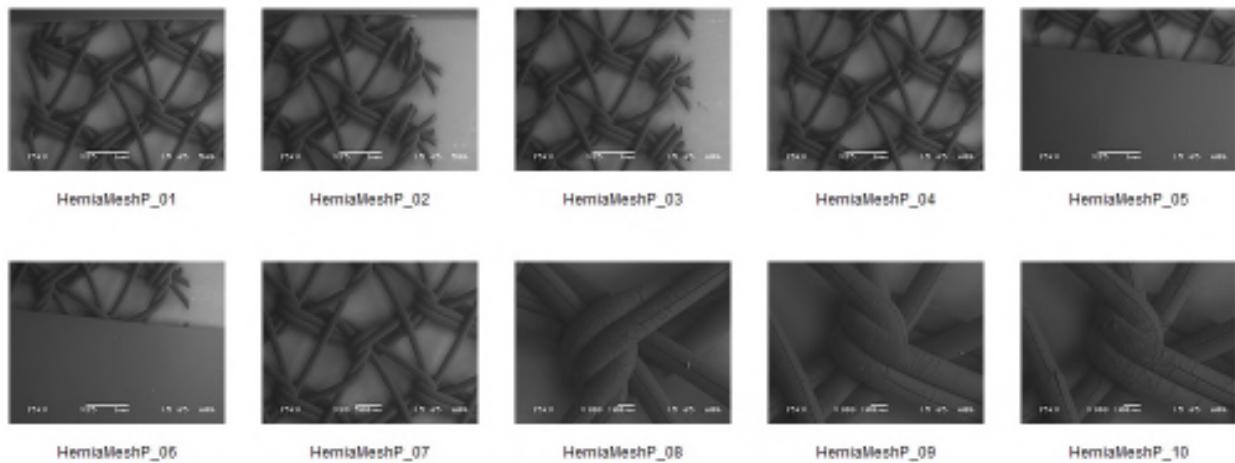
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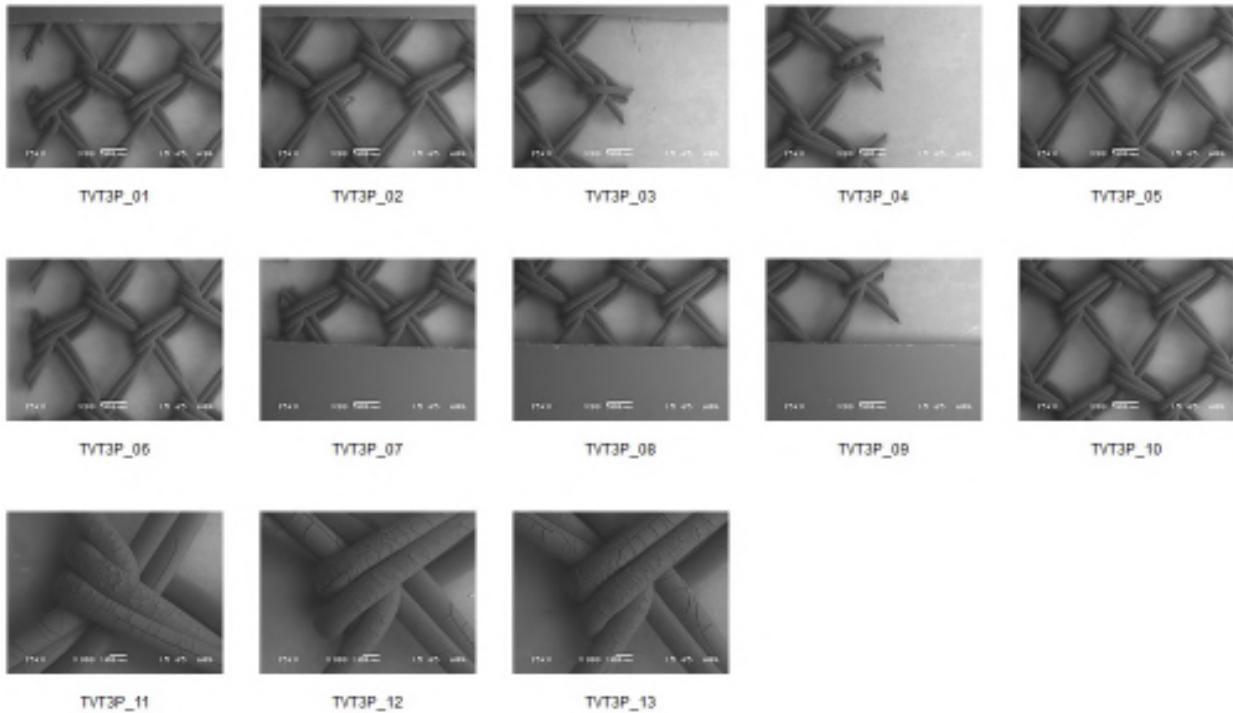


IMG\_1013











IMG\_2314



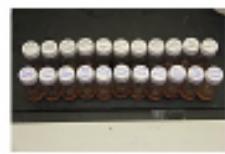
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IMG\_2316



IMG\_2317



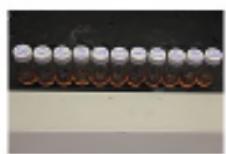
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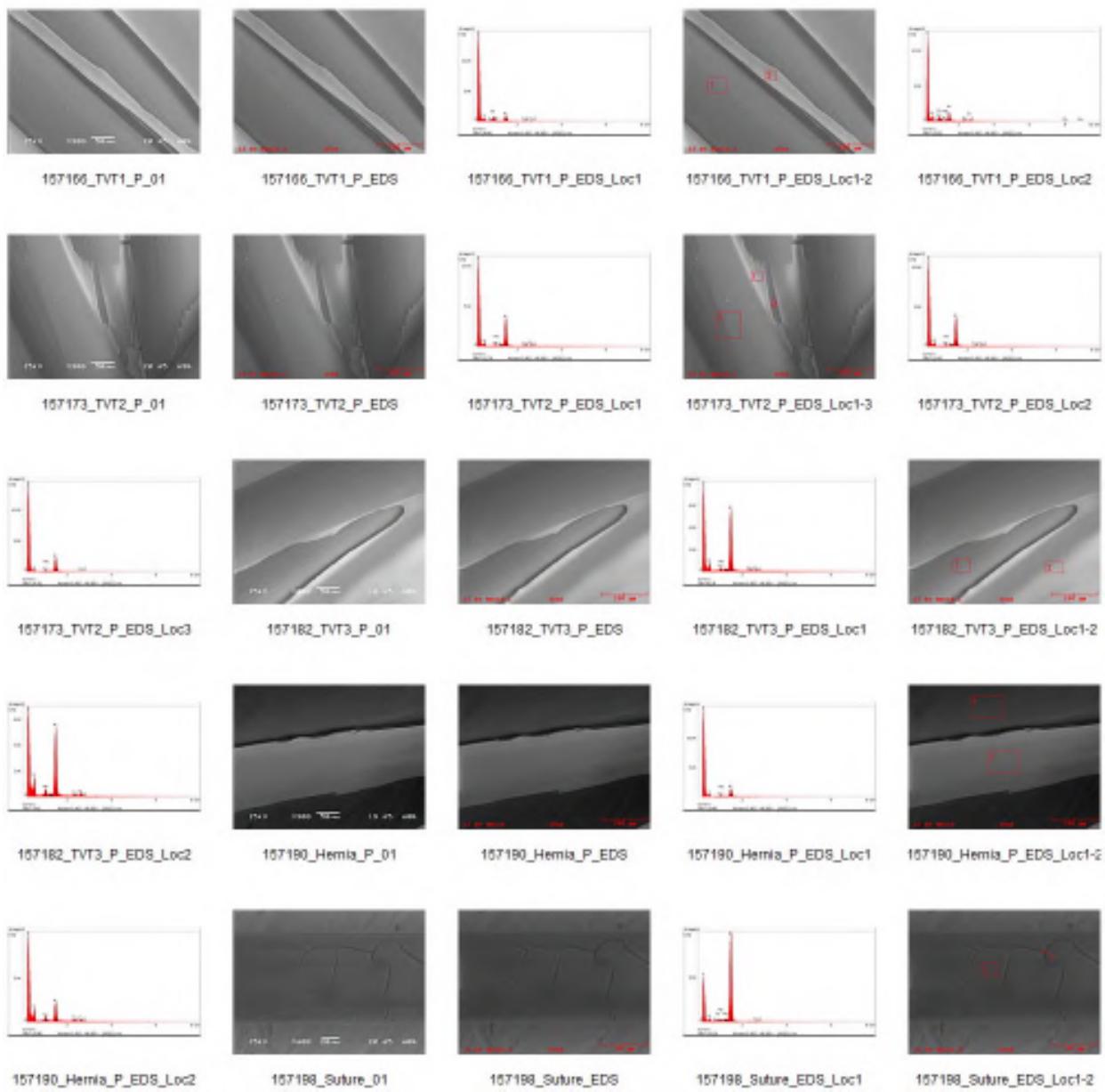
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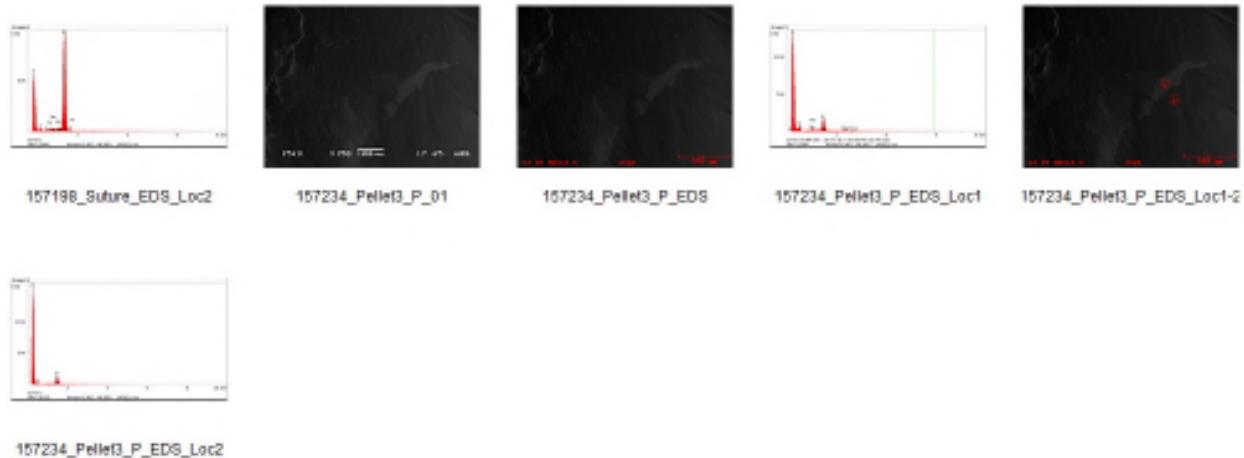


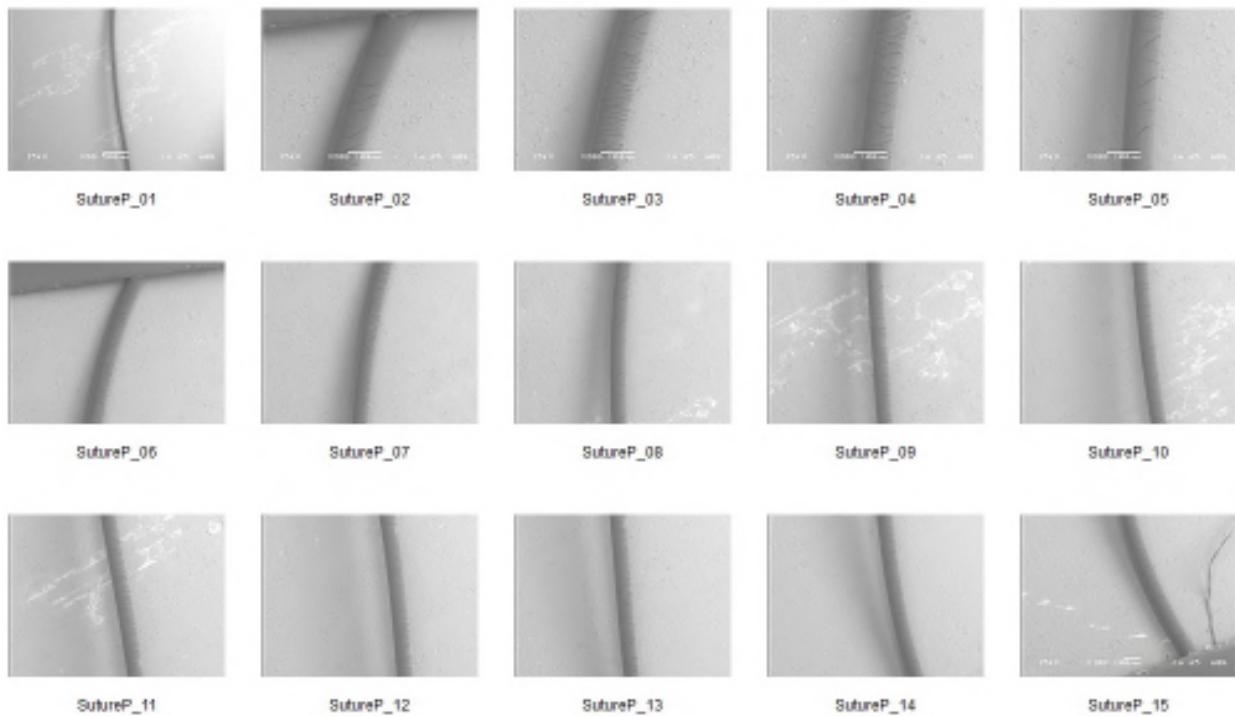
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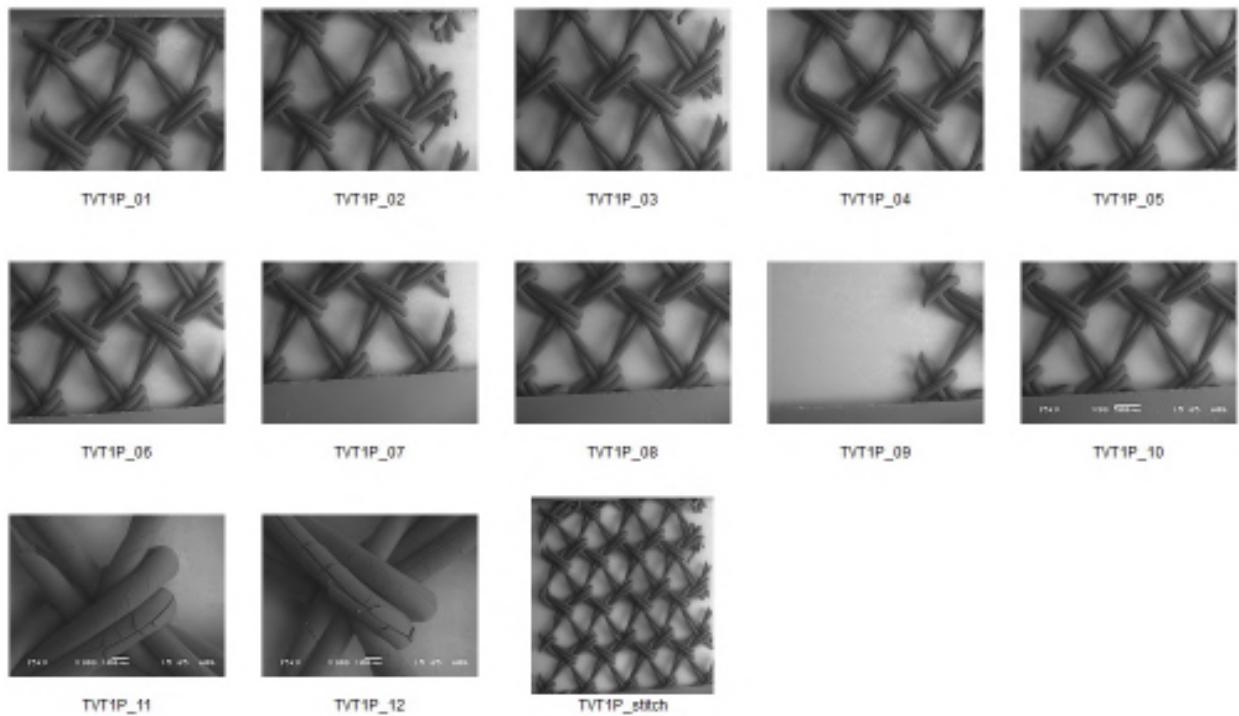


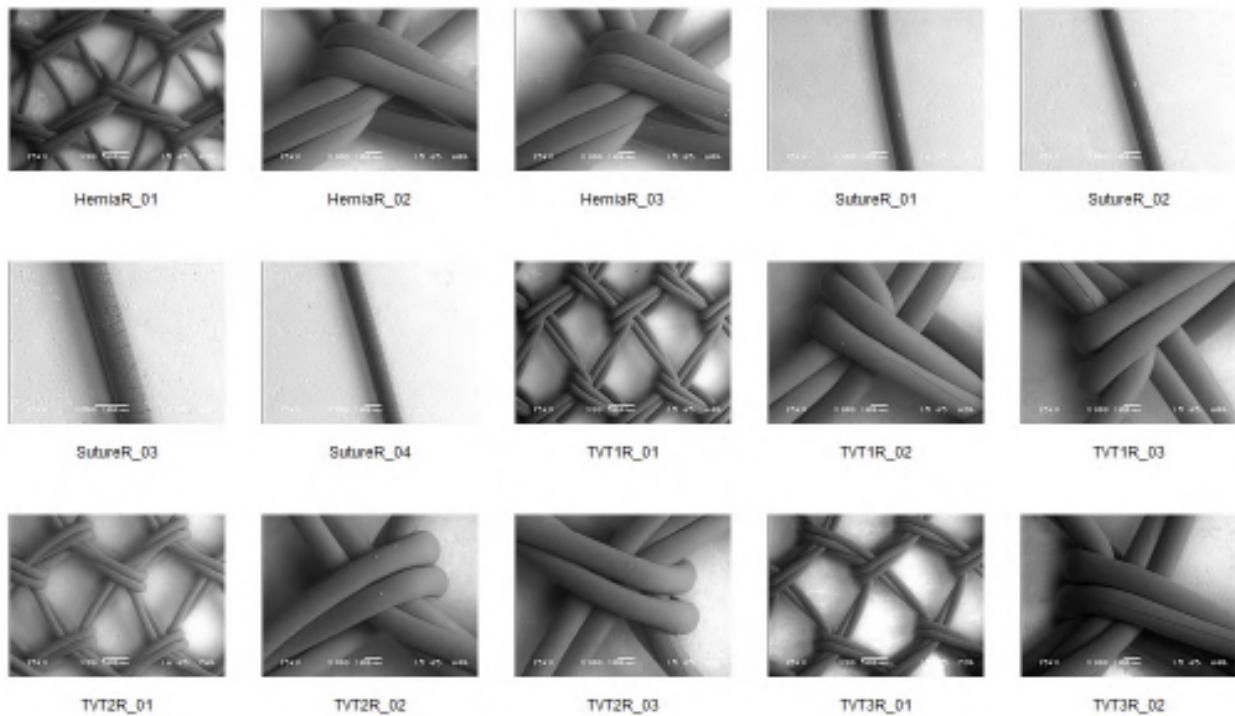
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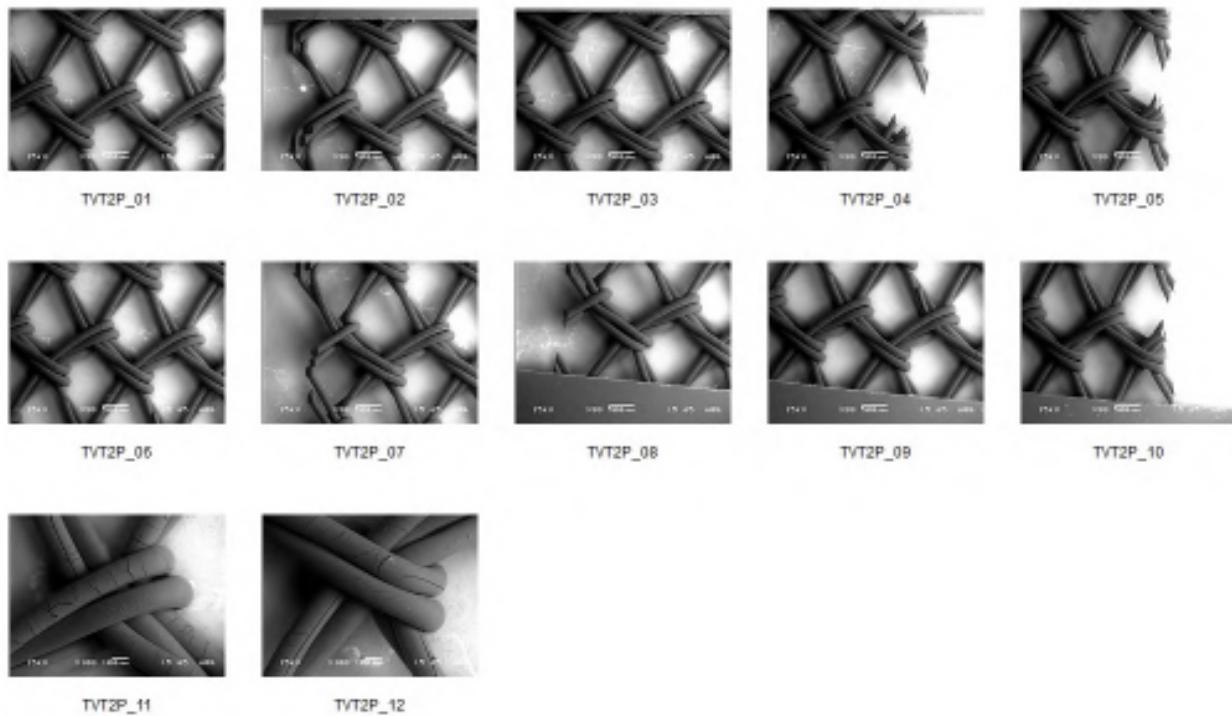














DSC\_7105



DSC\_7106



DSC\_7107



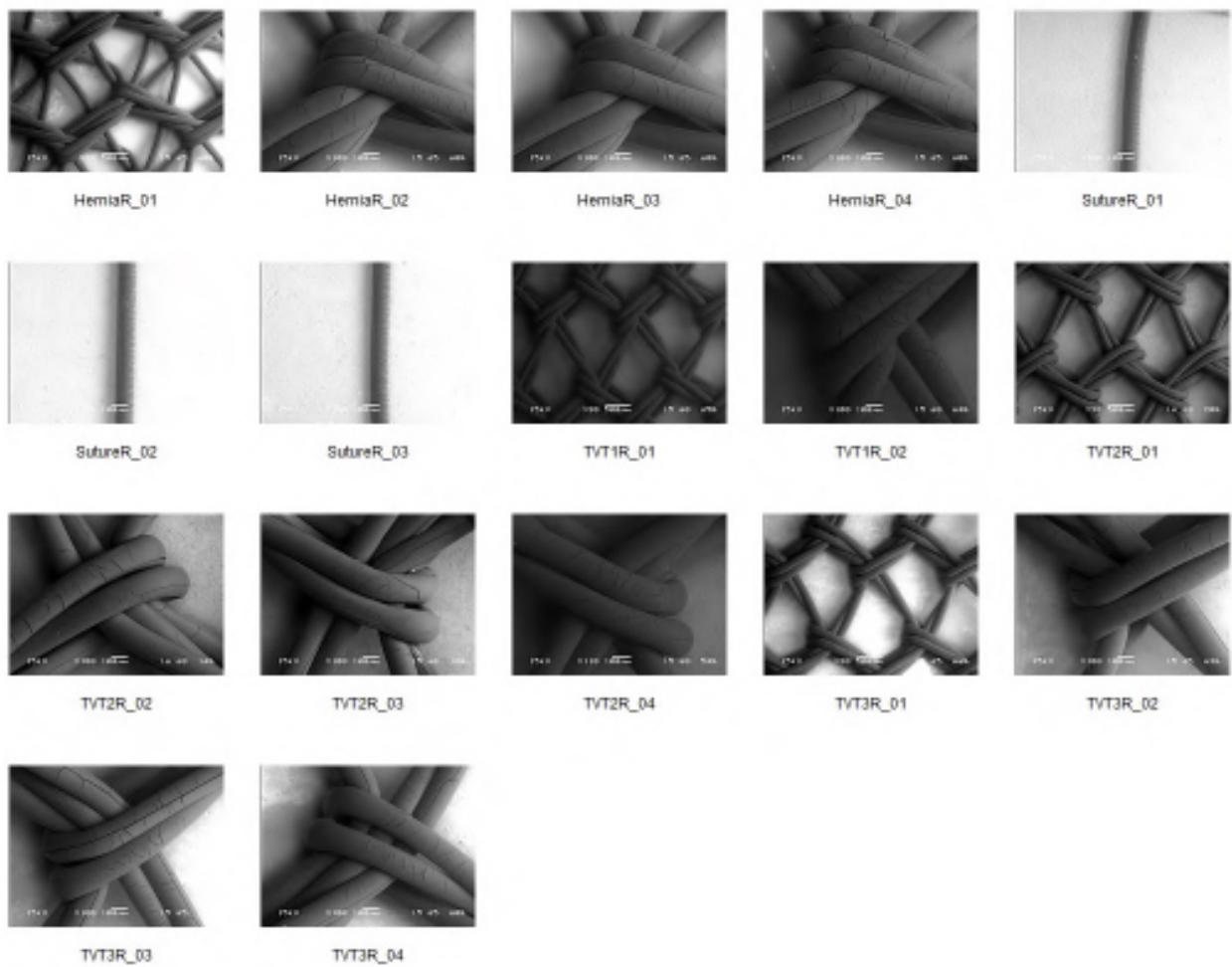
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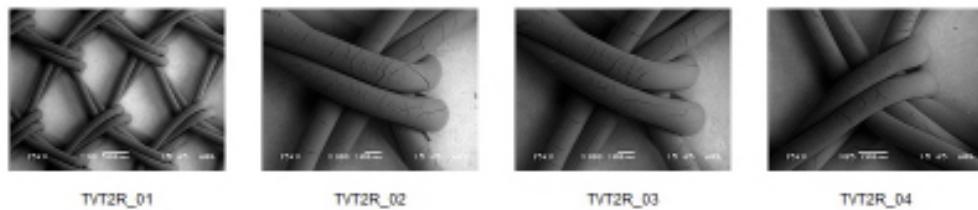


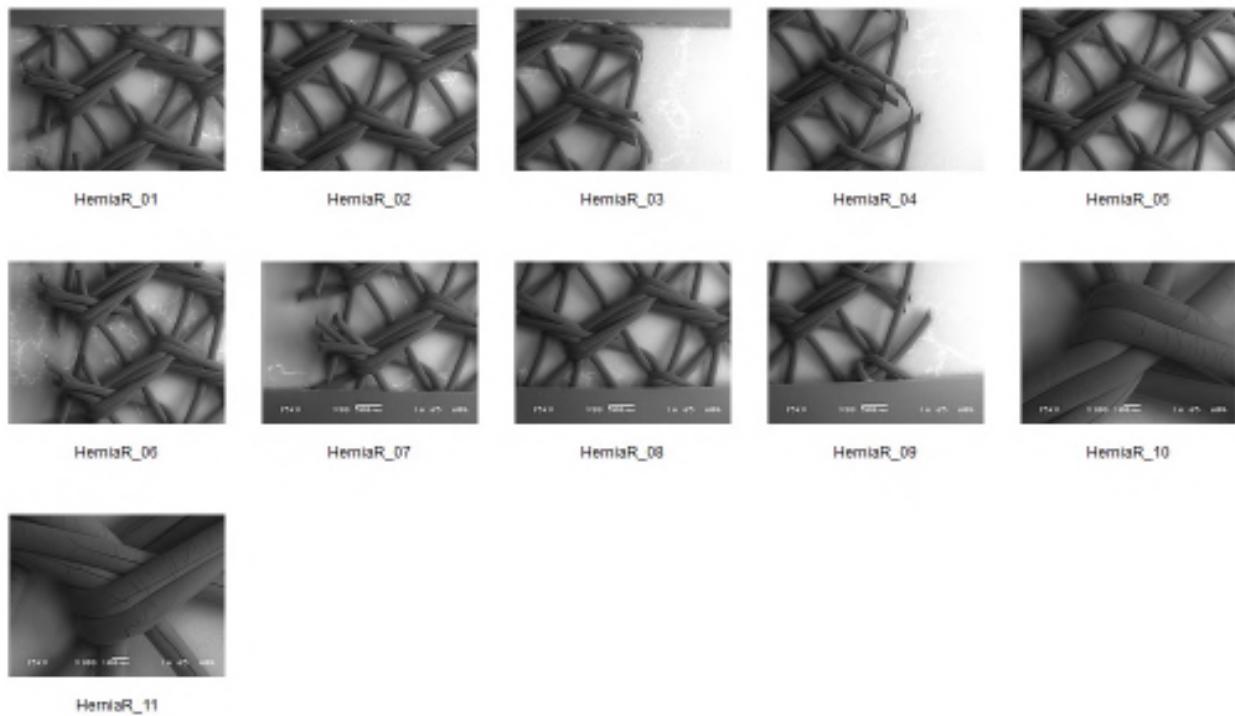
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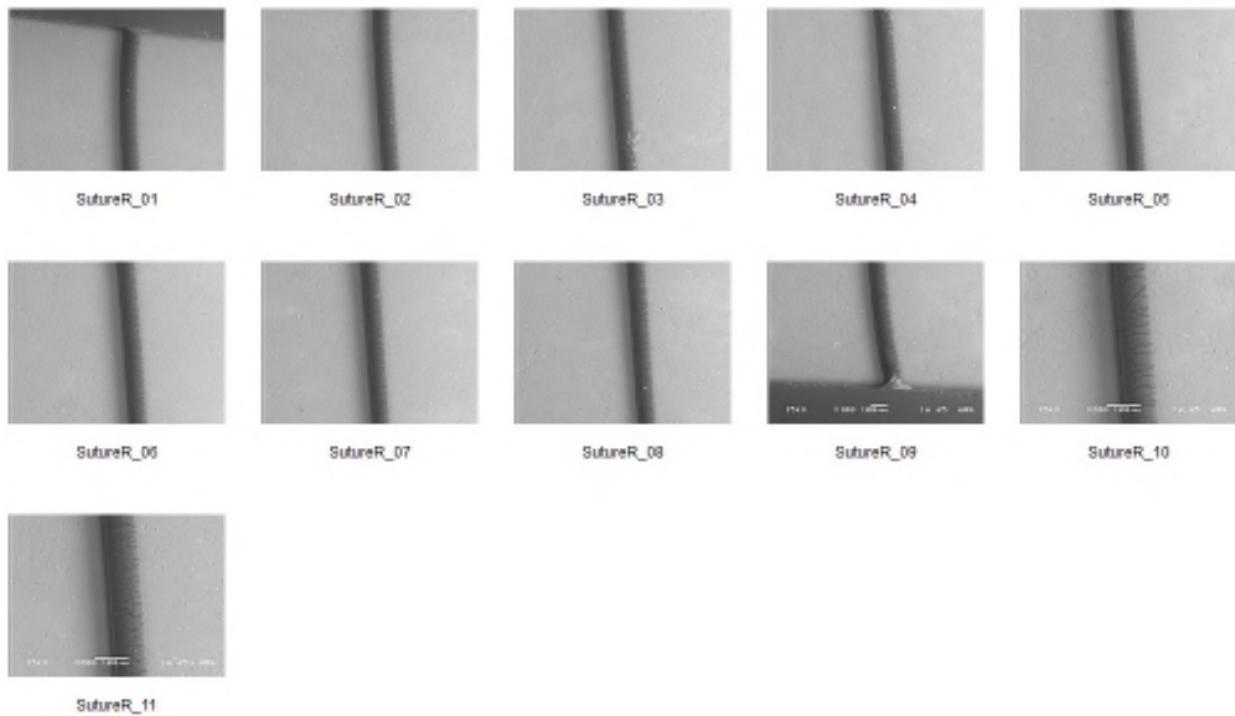


DSC\_7110



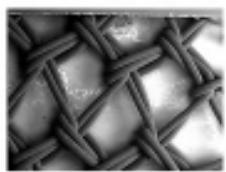








TVT1R\_01



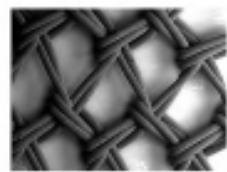
TVT1R\_02



TVT1R\_03



TVT1R\_04



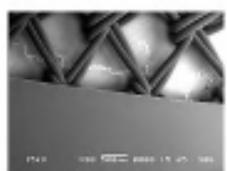
TVT1R\_05



TVT1R\_06



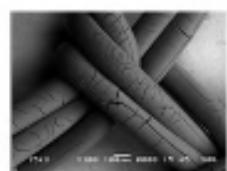
TVT1R\_07



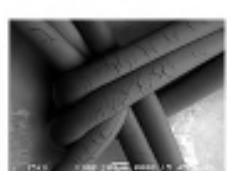
TVT1R\_08



TVT1R\_09



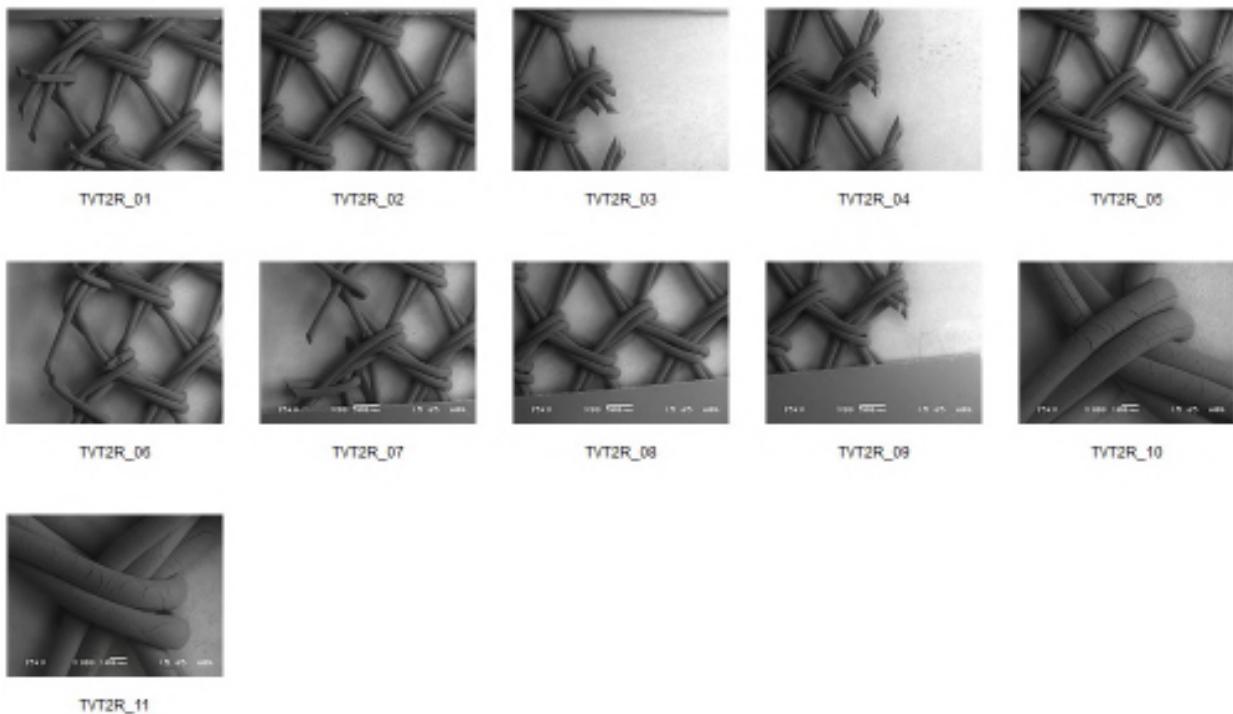
TVT1R\_10

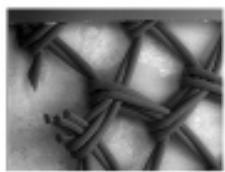


TVT1R\_11

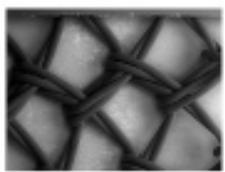


TVT1R\_stitch

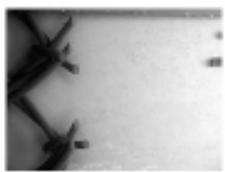




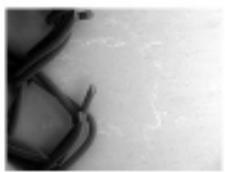
TVT3R\_01



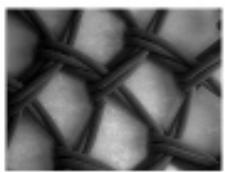
TVT3R\_02



TVT3R\_03



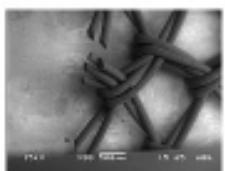
TVT3R\_04



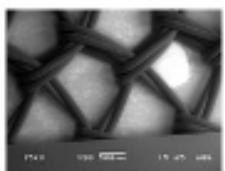
TVT3R\_05



TVT3R\_06



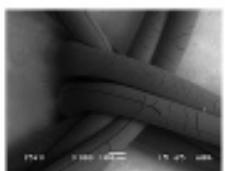
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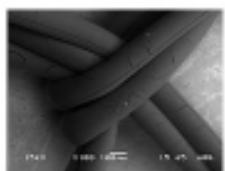
TVT3R\_08



TVT3R\_09



TVT3R\_10



TVT3R\_11



DSC\_9597



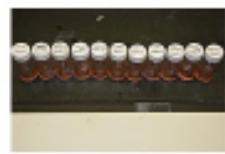
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DSC\_9599



DSC\_9600



DSC\_9601



DSC\_9683



DSC\_9684



DSC\_9685



DSC\_9686



DSC\_9687



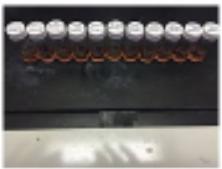
DSC\_9688



DSC\_9689



IMG\_1054



IMG\_1055



IMG\_1056



IMG\_1057



IMG\_1058



DSC\_9696



DSC\_9697



DSC\_9698



DSC\_9699



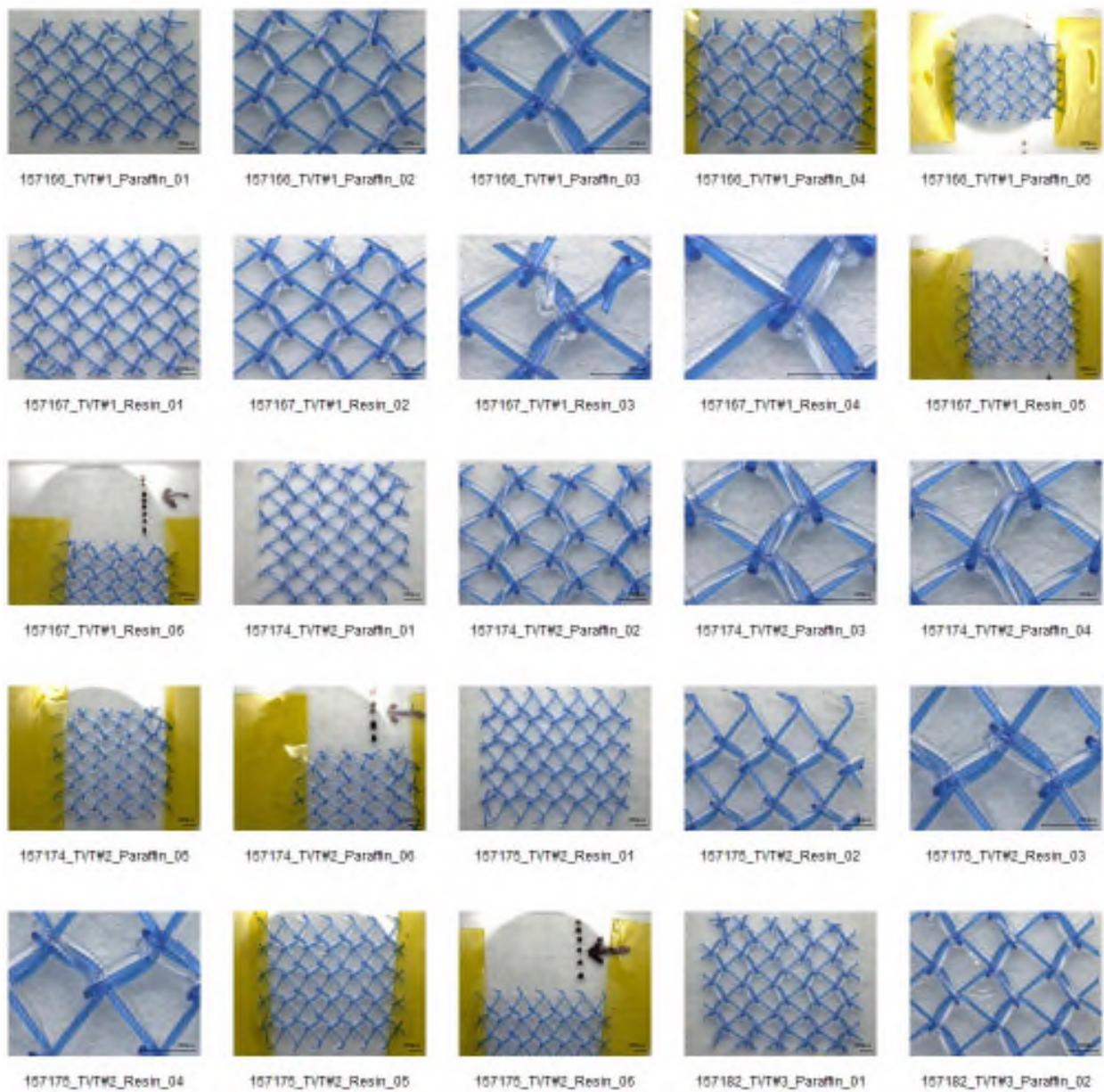
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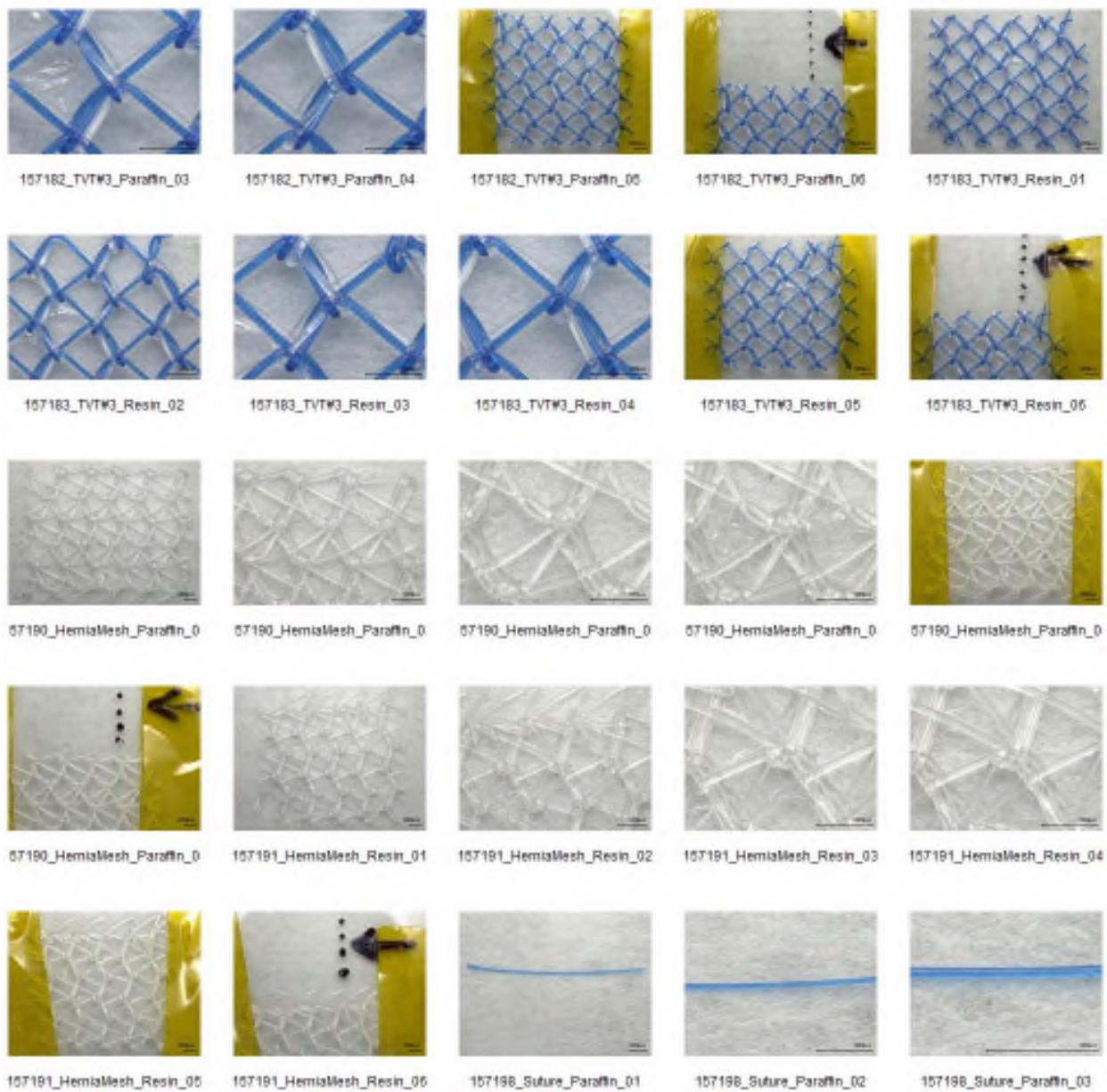


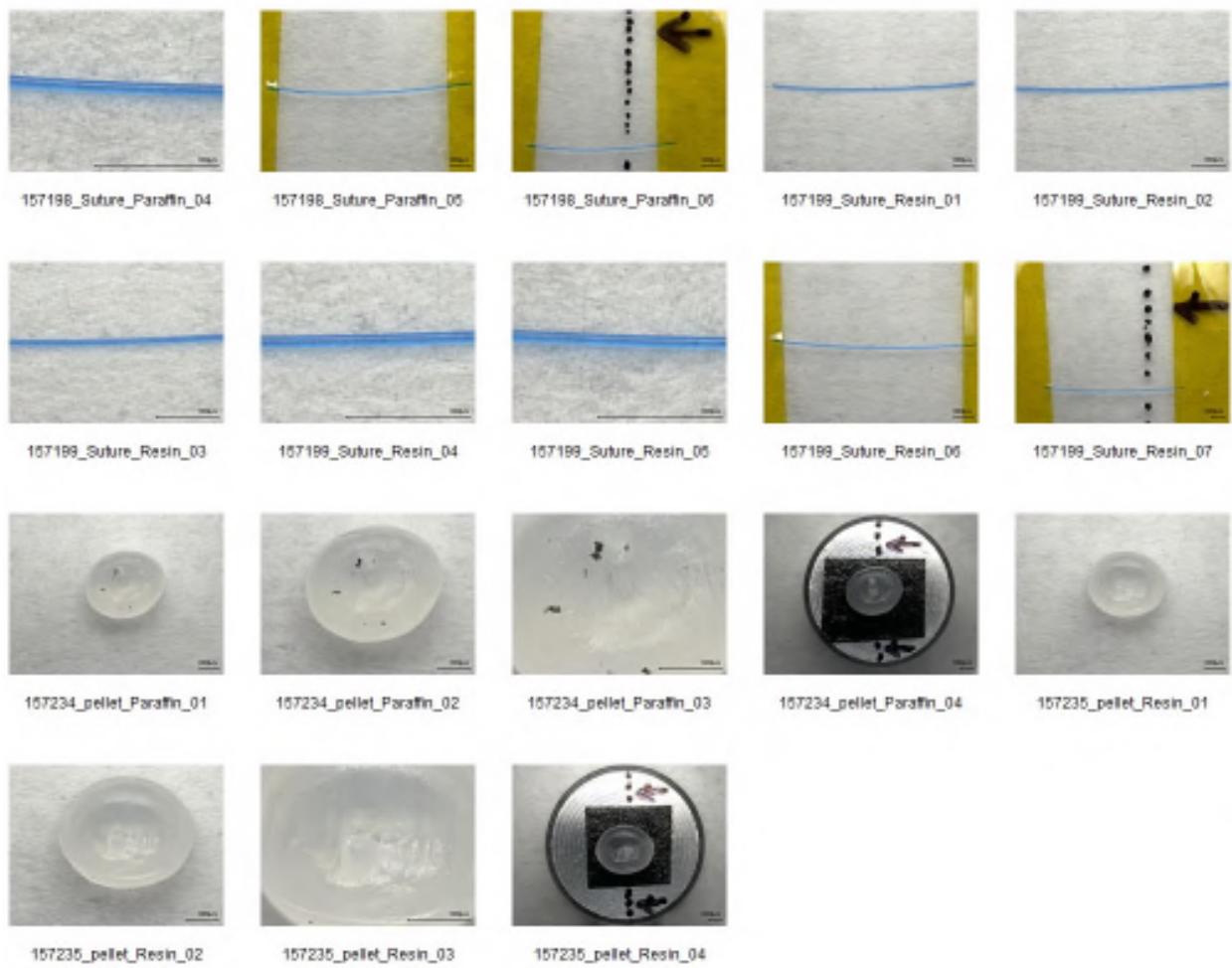
DSC\_9701



DSC\_9702









DSC\_4479



DSC\_4480



DSC\_4481



DSC\_4482



DSC\_4483





DSC\_4533



DSC\_4465



DSC\_4466



DSC\_4467



DSC\_4468



DSC\_4469



DSC\_4470



DSC\_4471



DSC\_4472



DSC\_4473



DSC\_4474



DSC\_4475



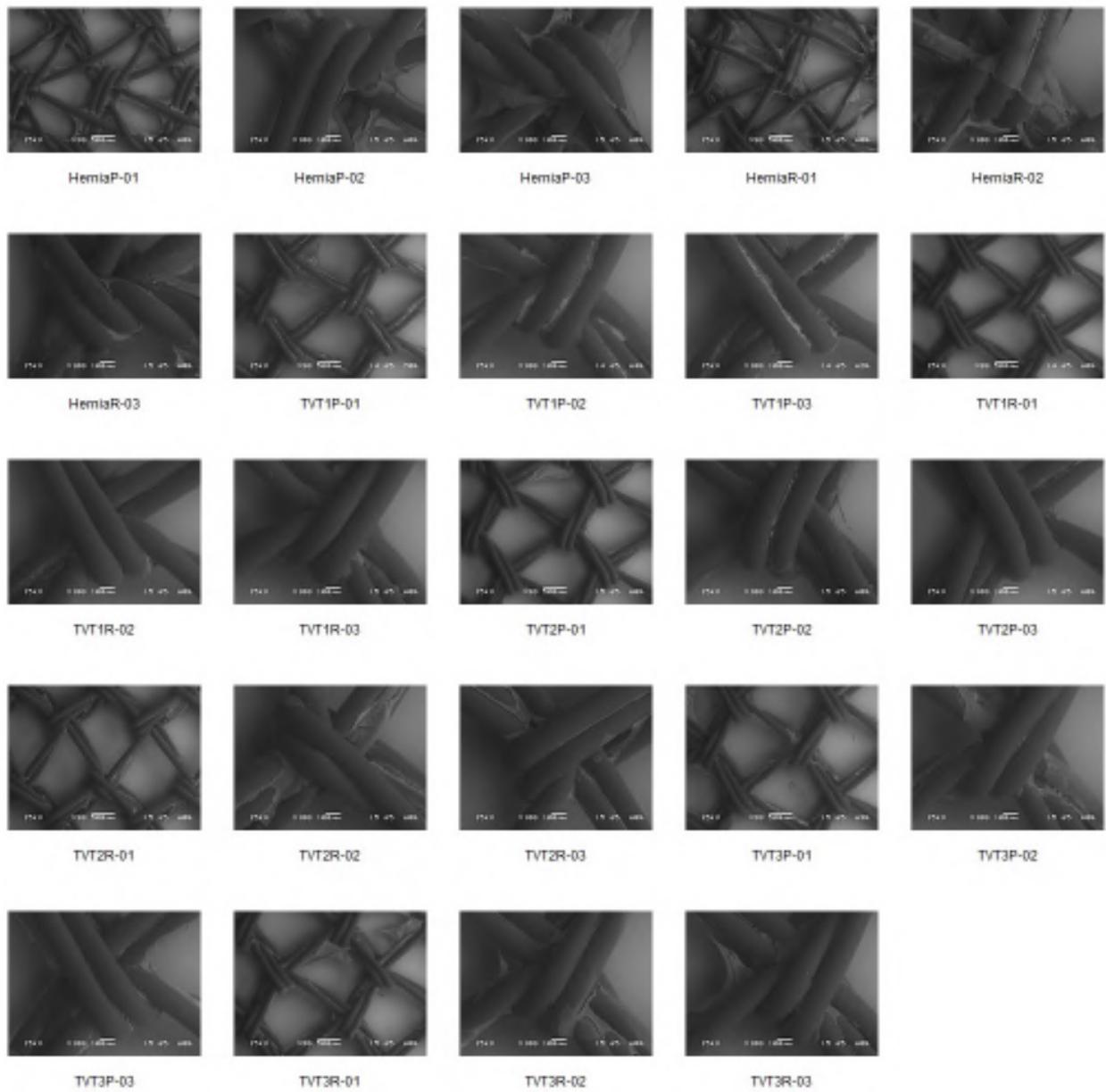
DSC\_4476



DSC\_4477



DSC\_4478





DSC\_4487



DSC\_4488



DSC\_4489



DSC\_4490



DSC\_4491



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DSC\_4493



DSC\_4494



DSC\_4495



DSC\_4496



DSC\_4497



DSC\_4498



DSC\_4499



DSC\_4500



DSC\_4501



DSC\_4502



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DSC\_4504



DSC\_4505



DSC\_4506



DSC\_4507



DSC\_4508



DSC\_4509



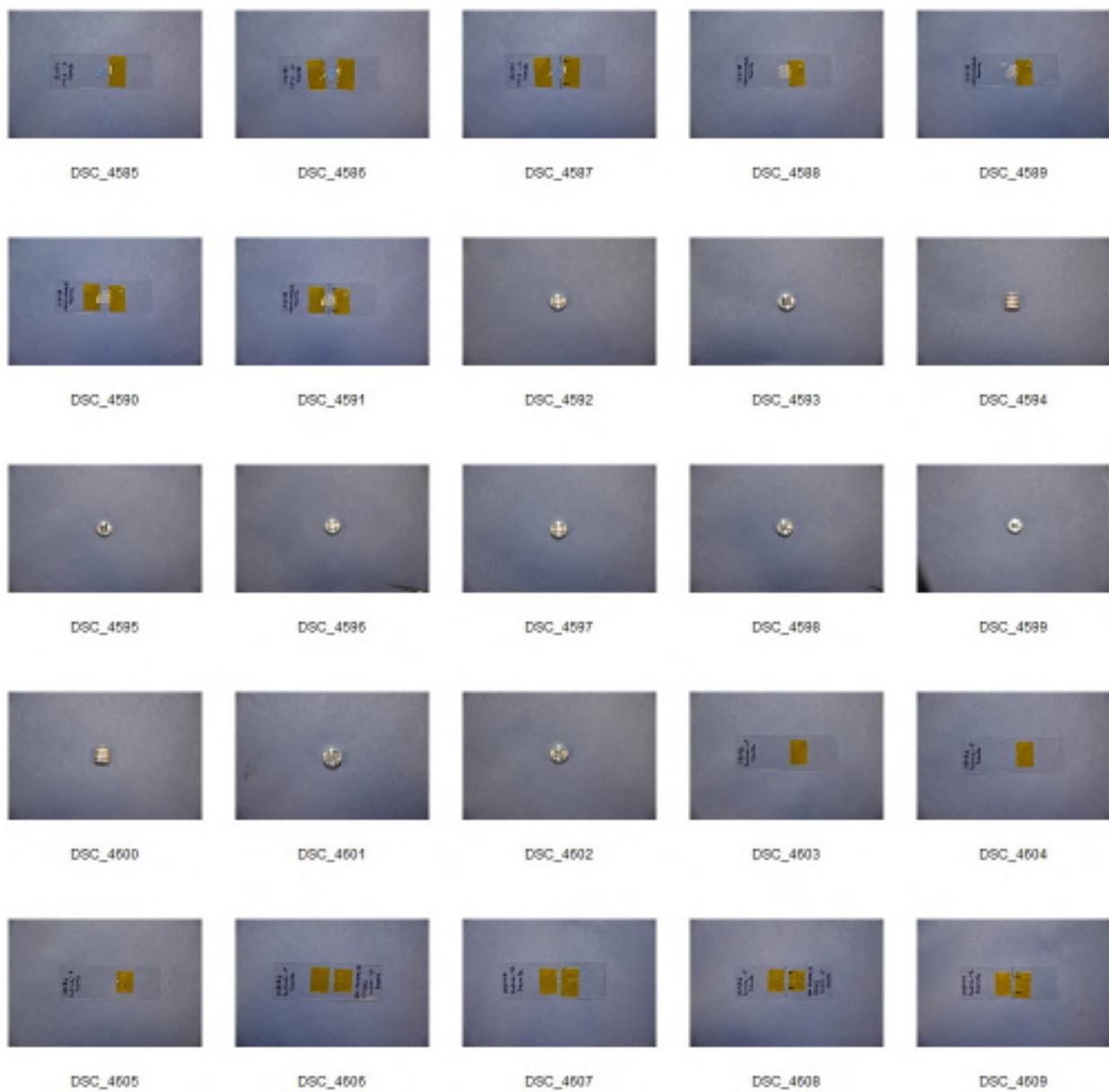
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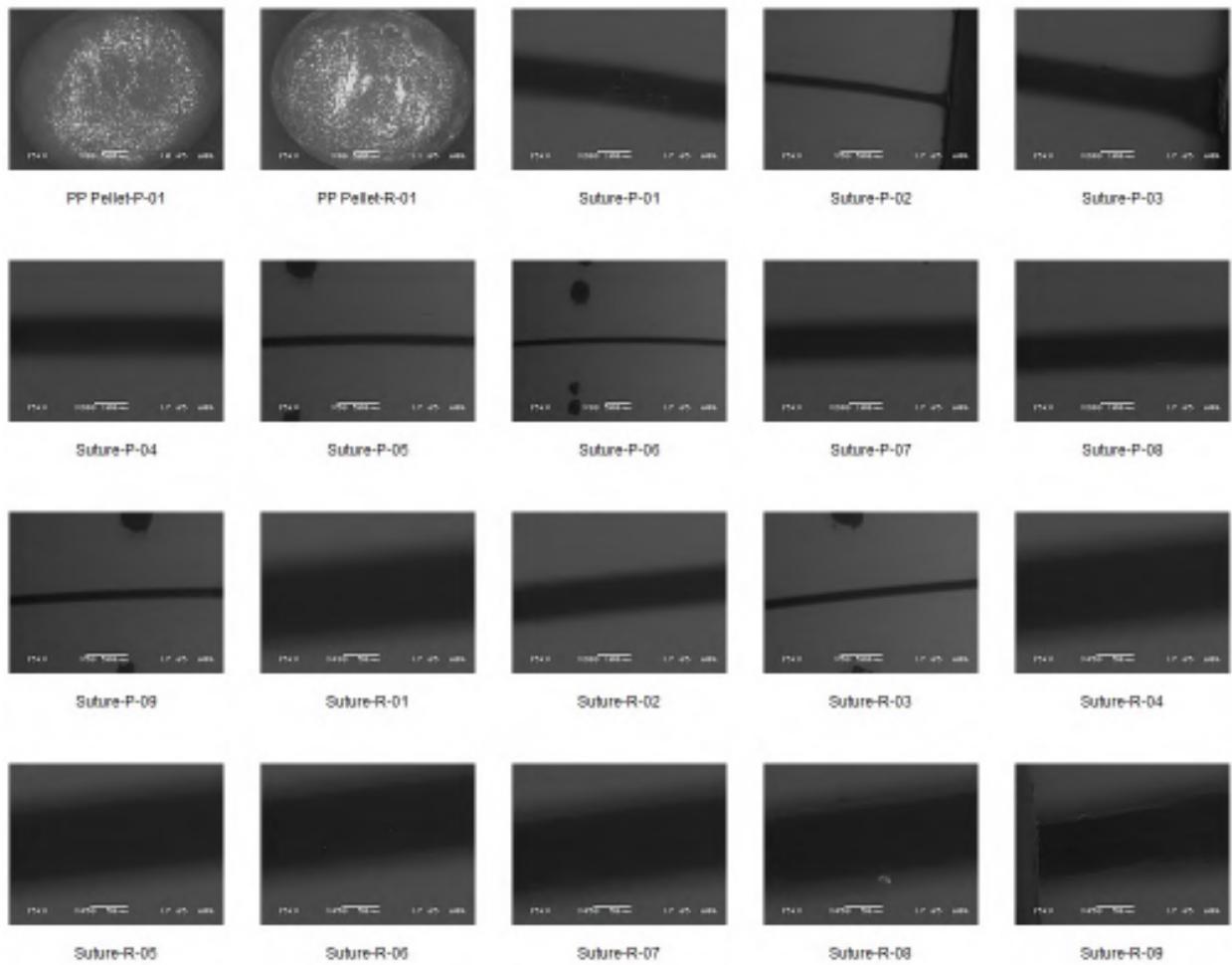
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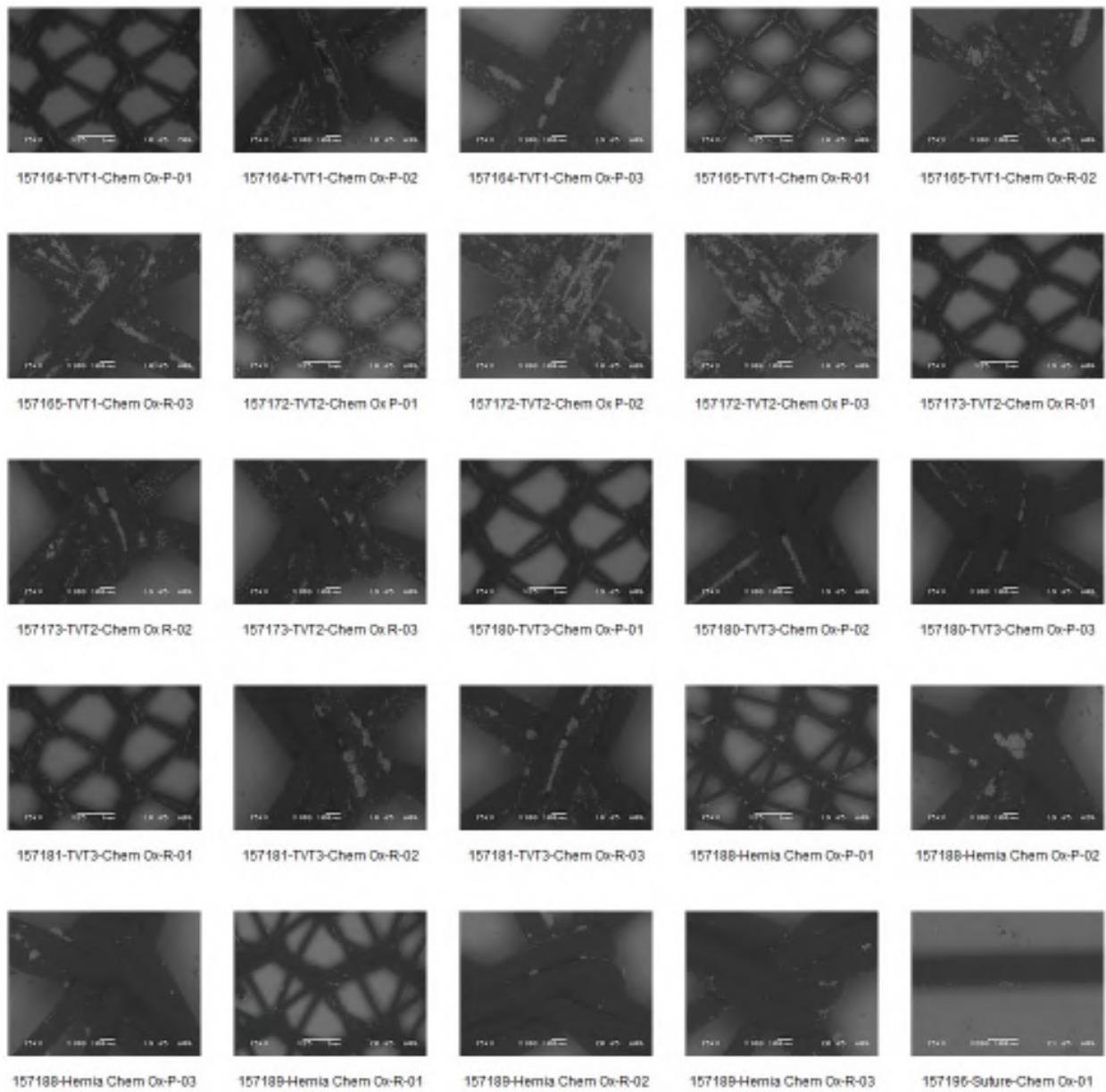


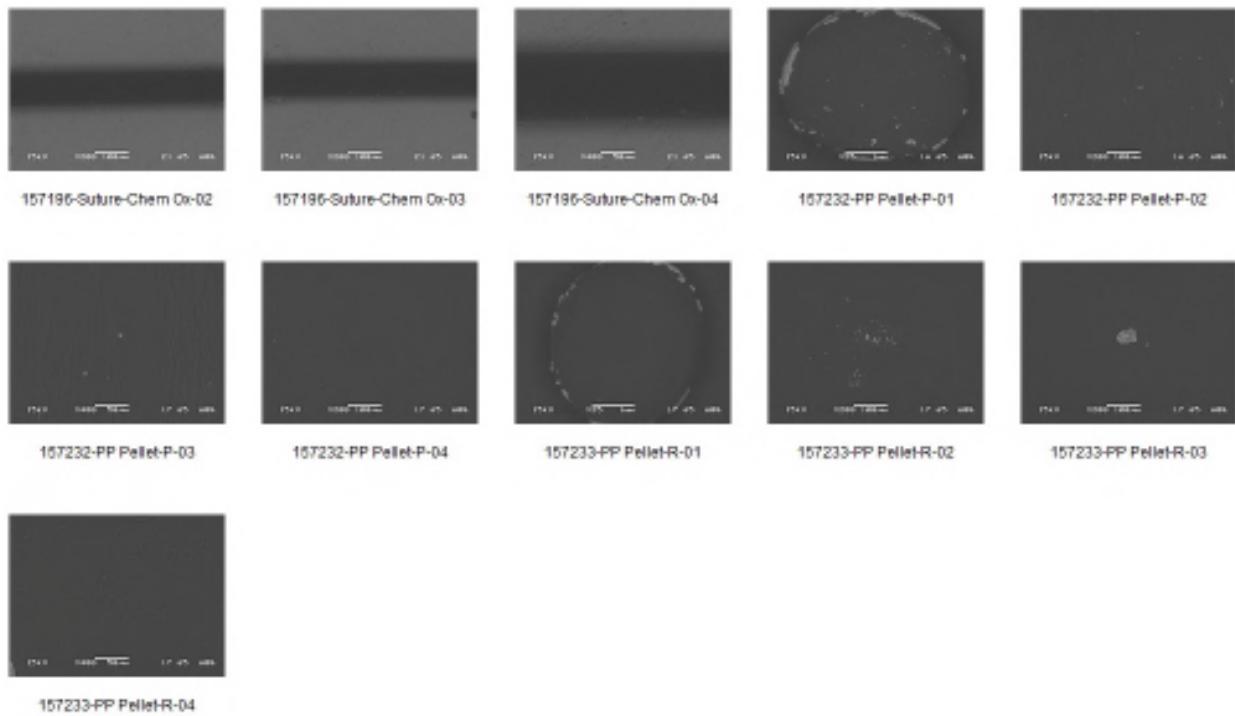


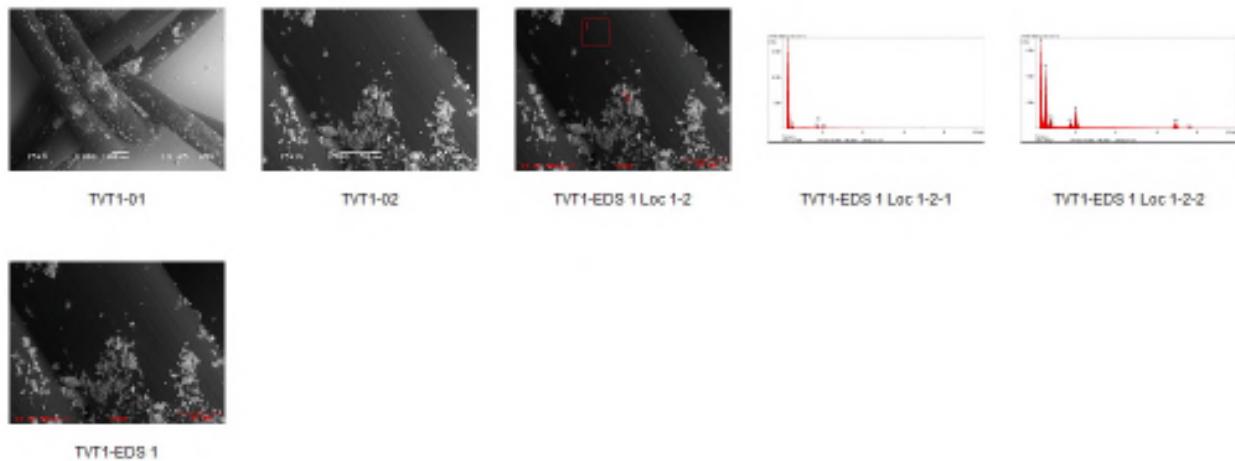


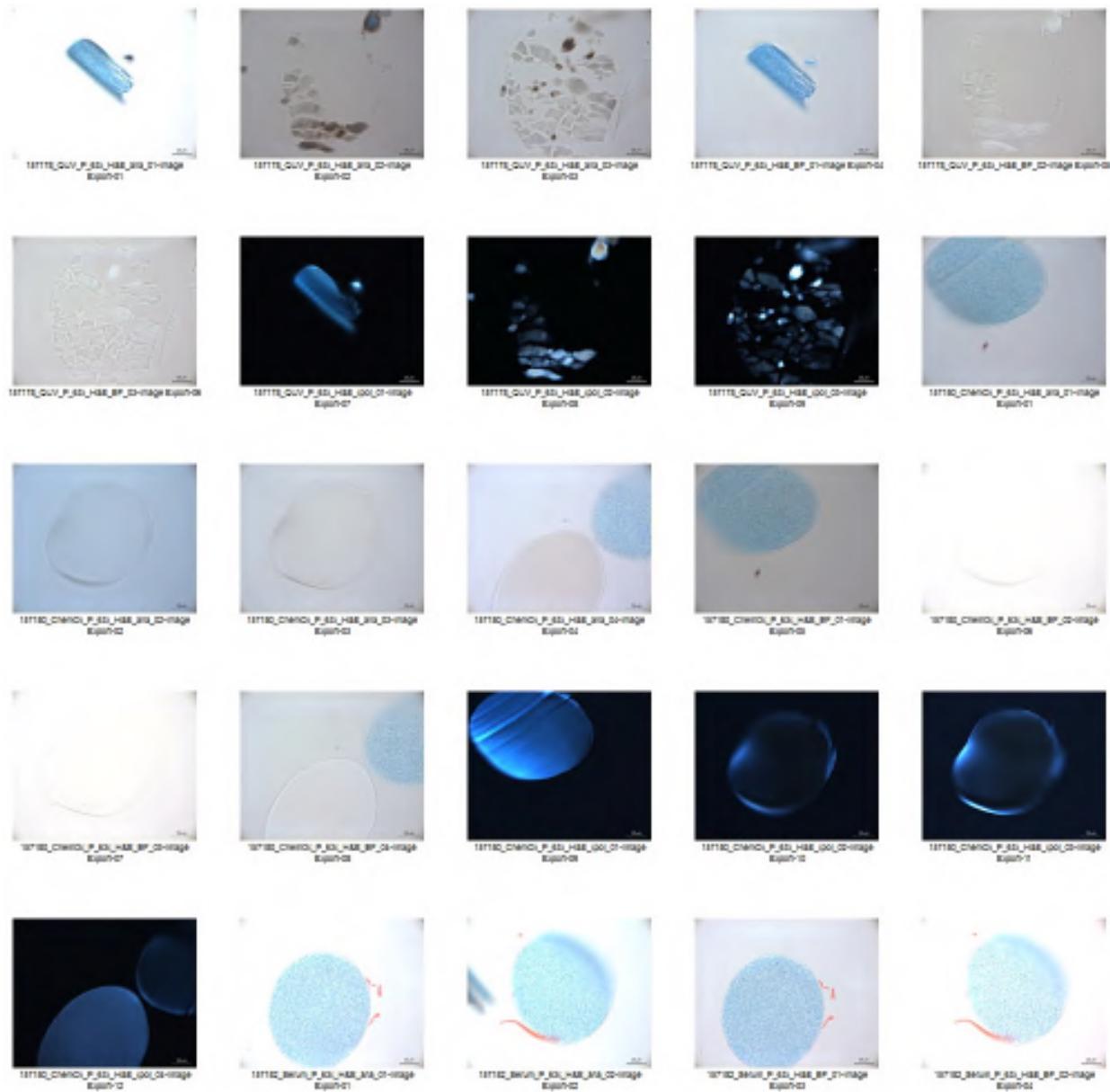


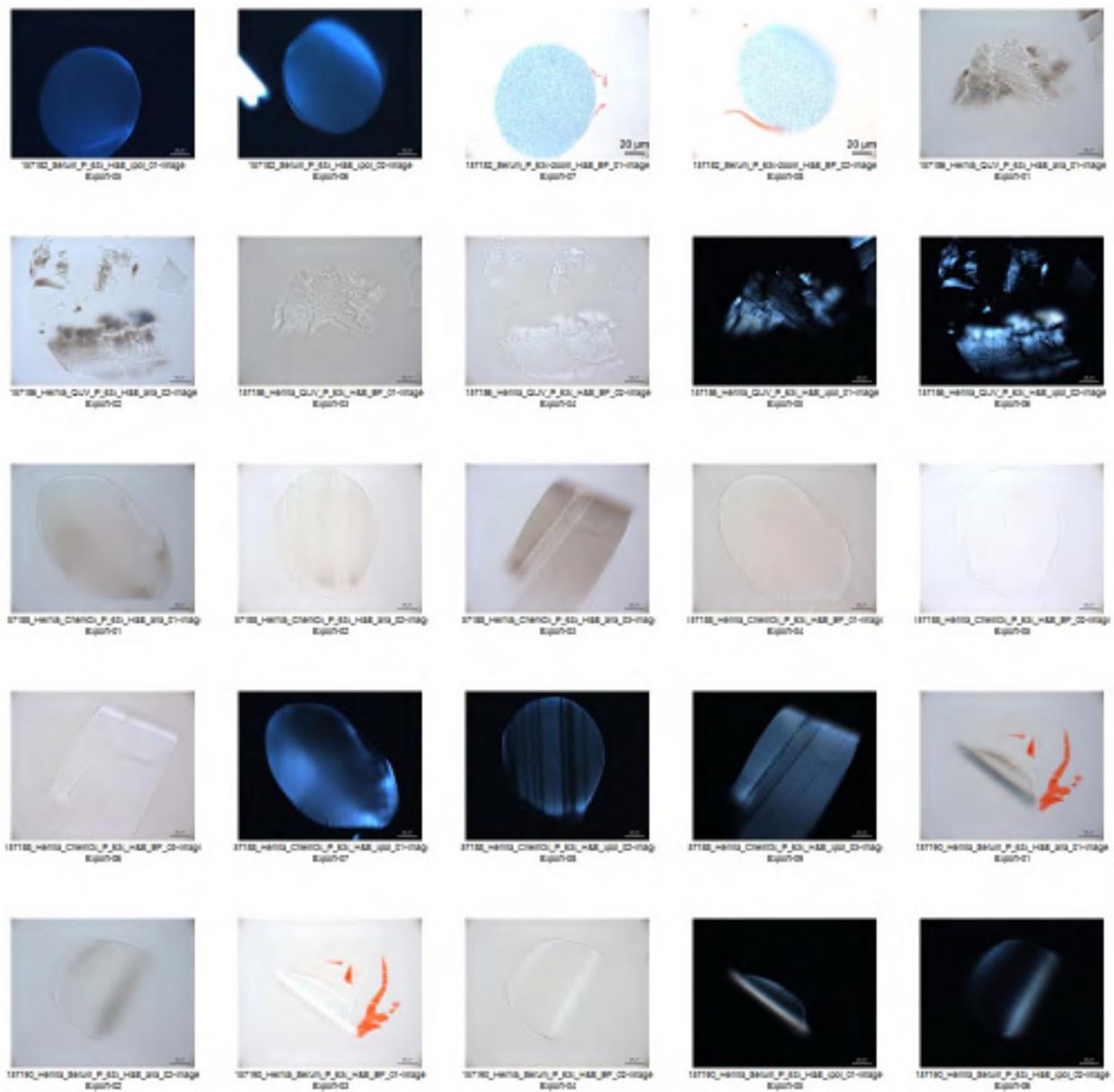


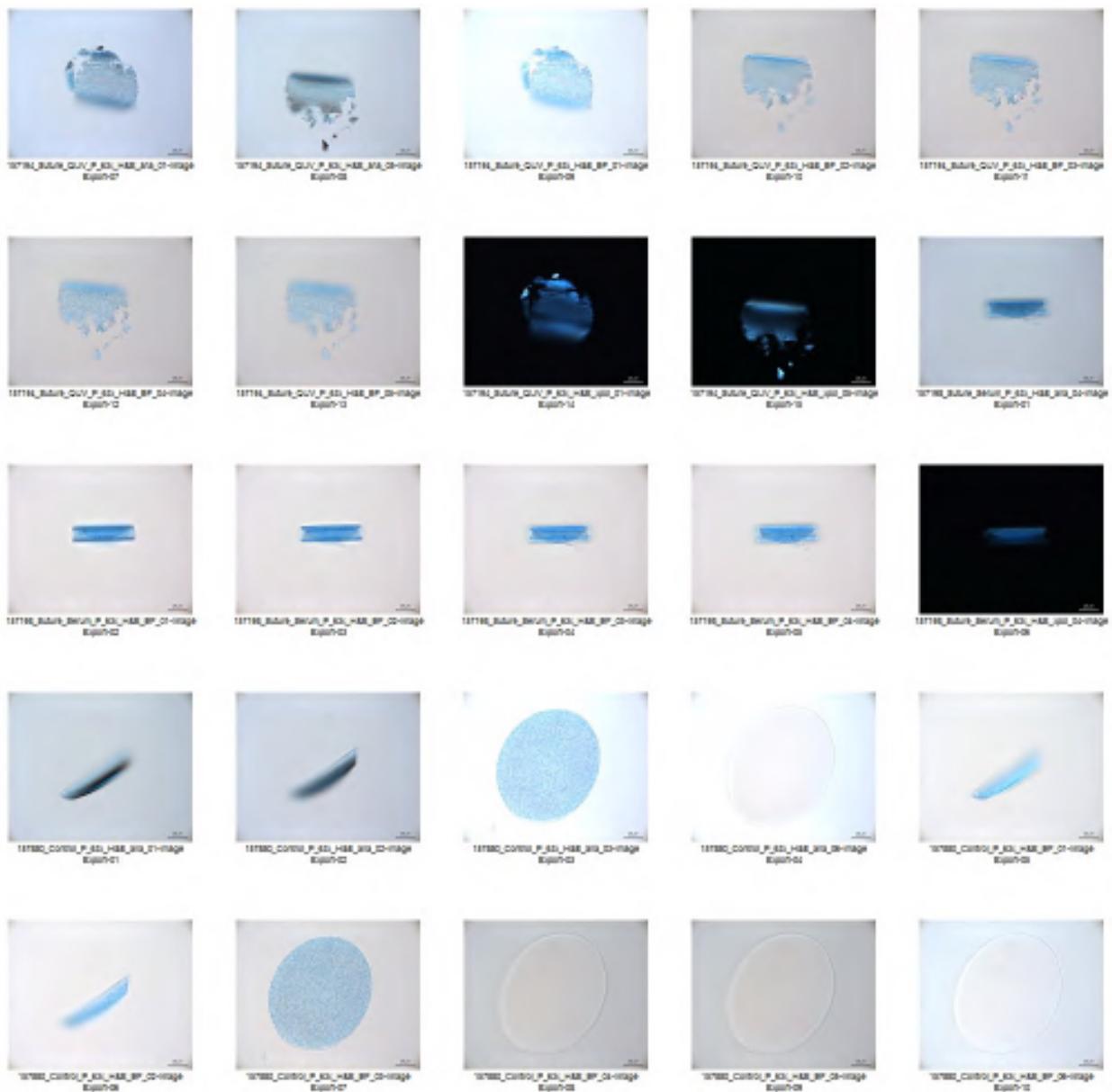


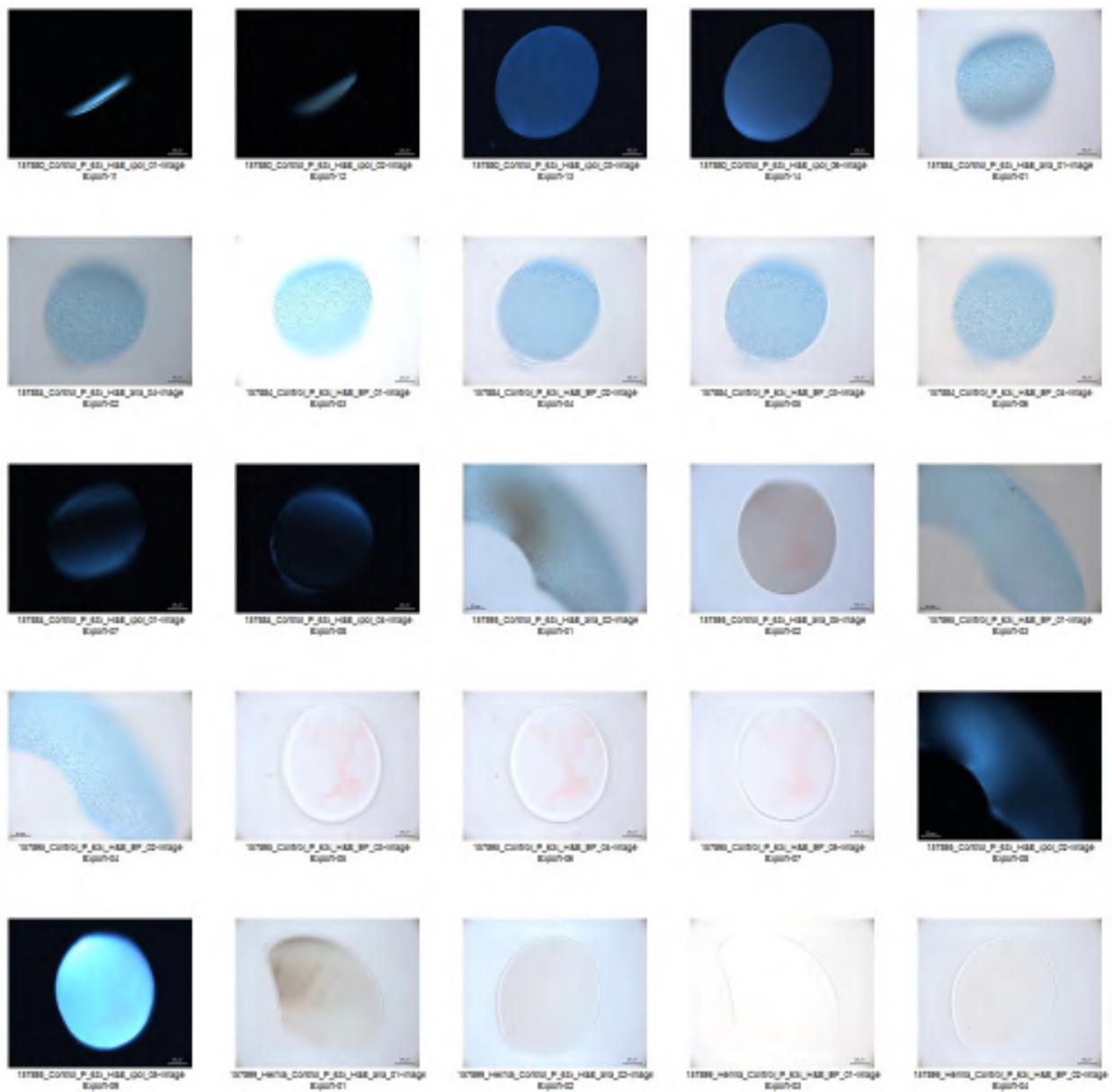


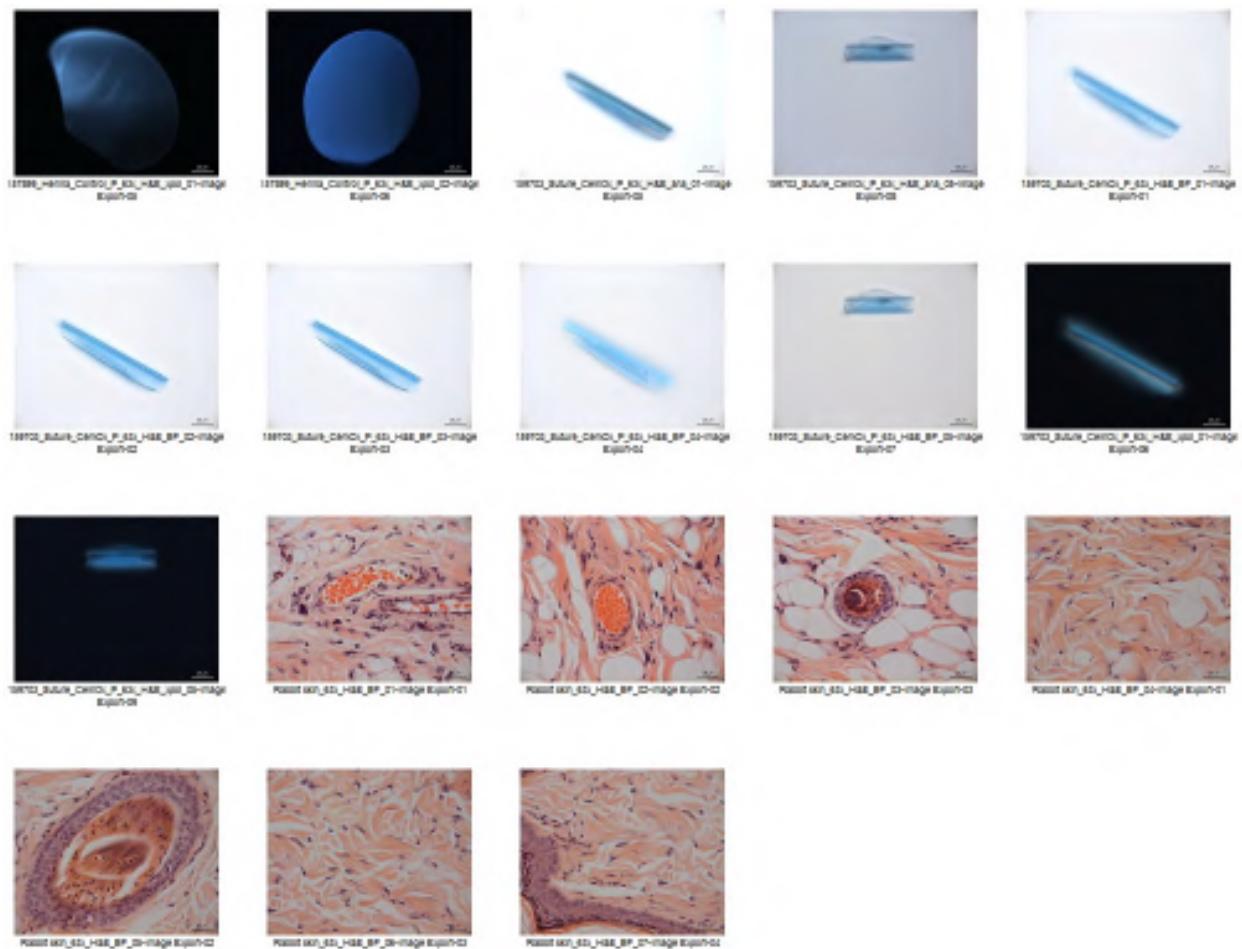


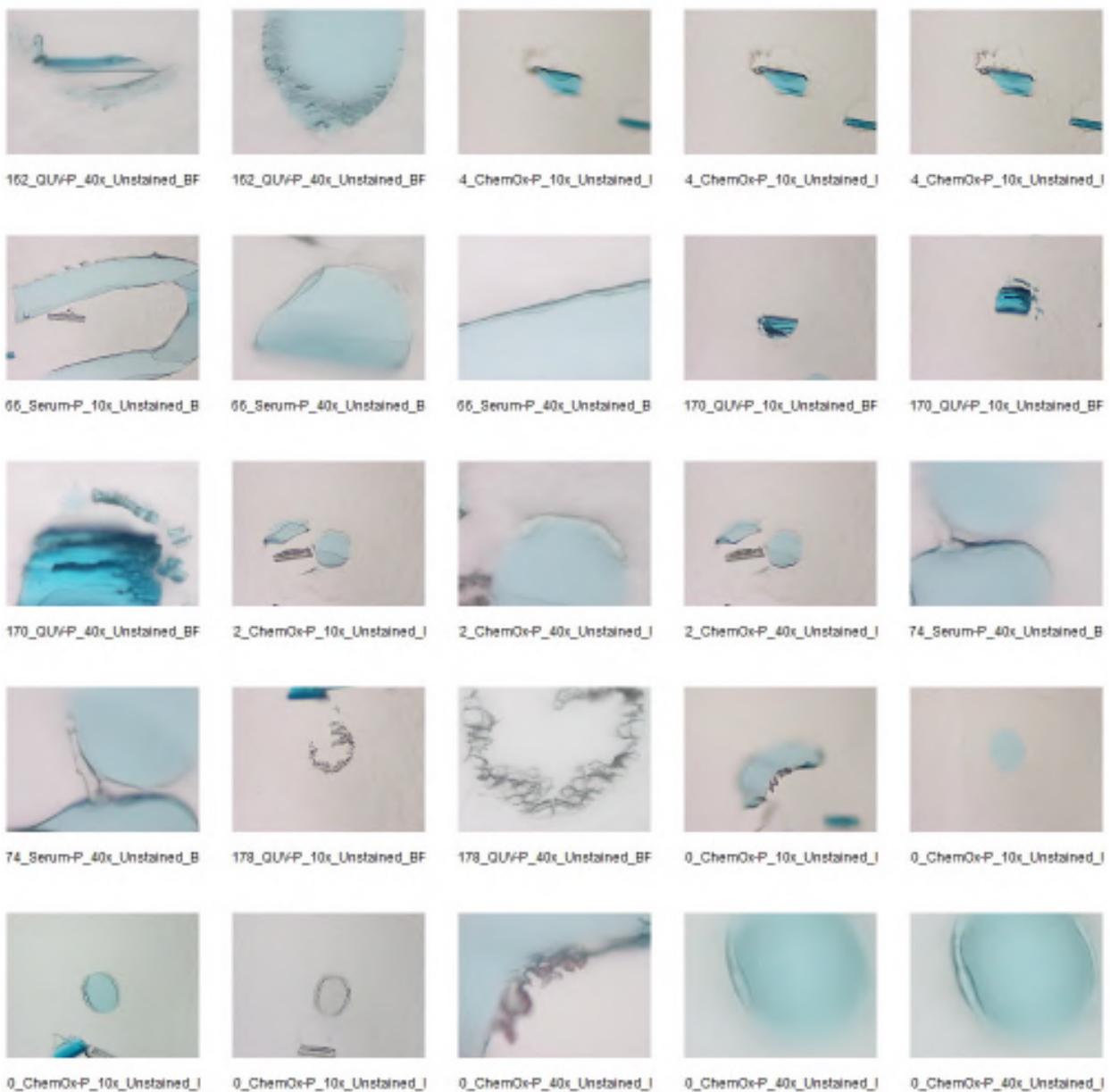


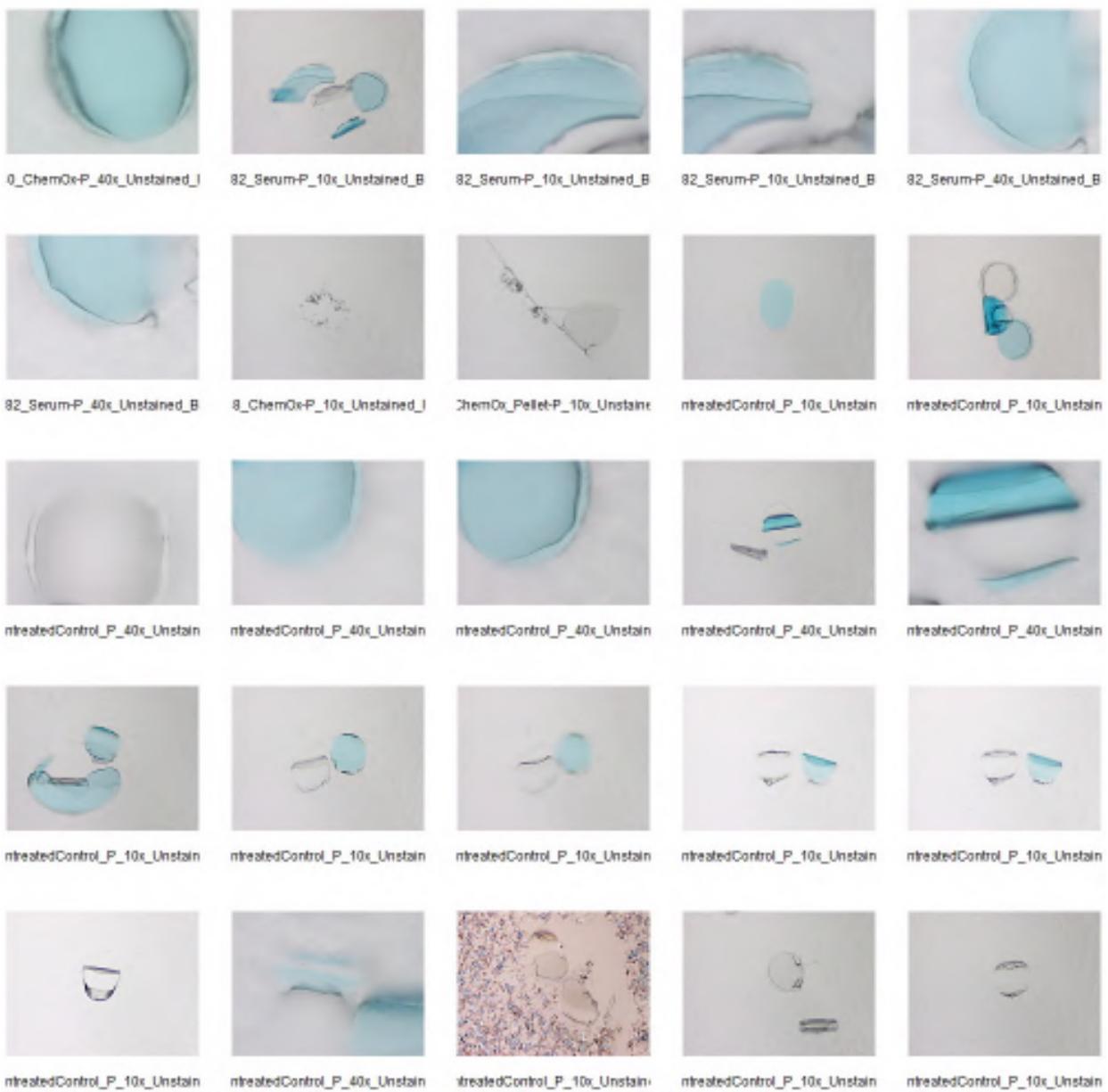














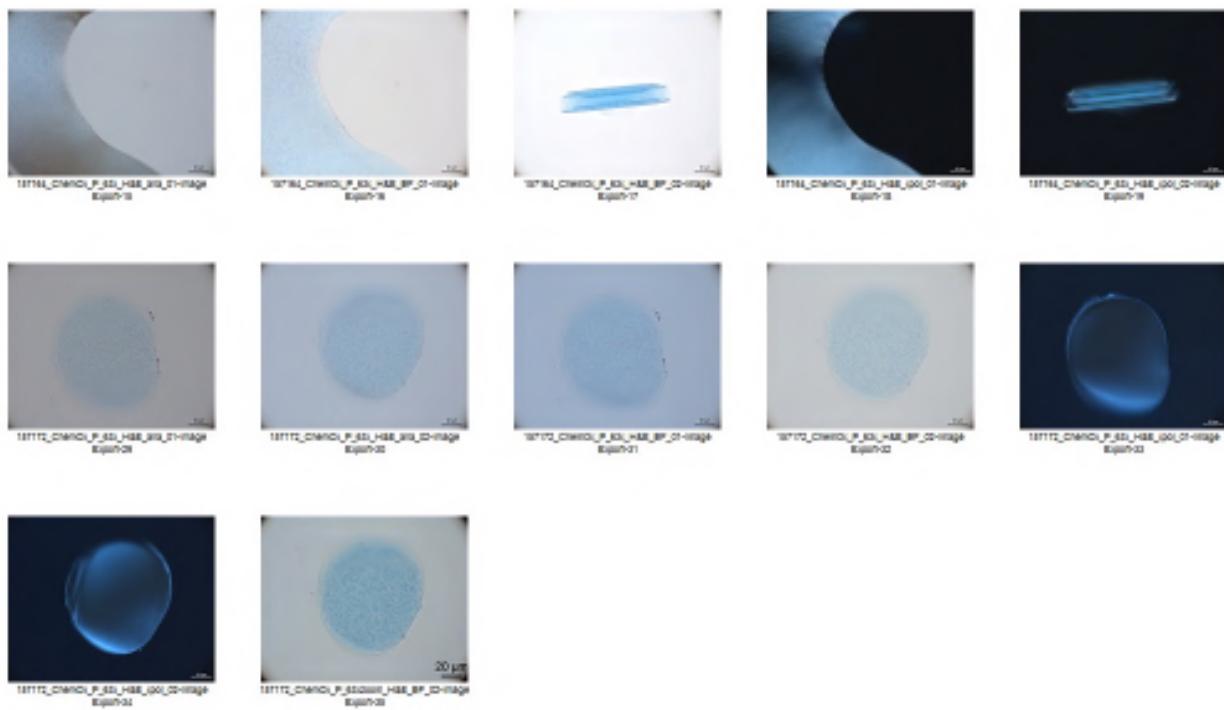
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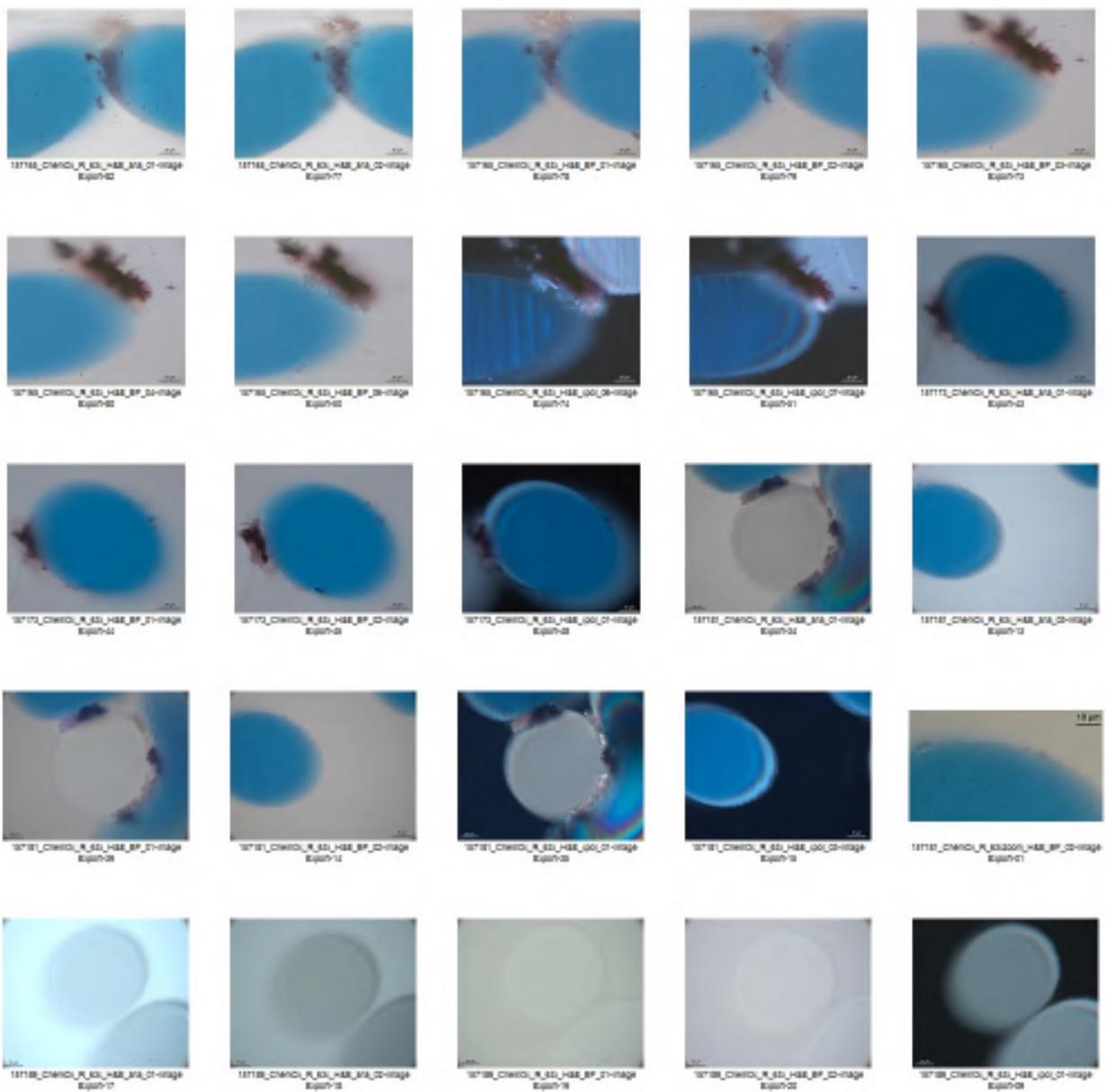
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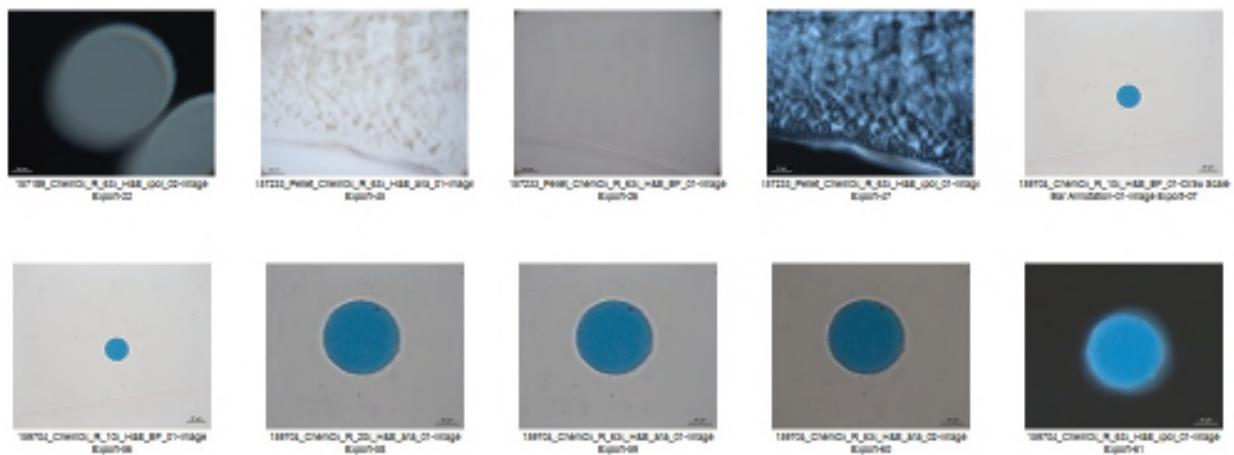
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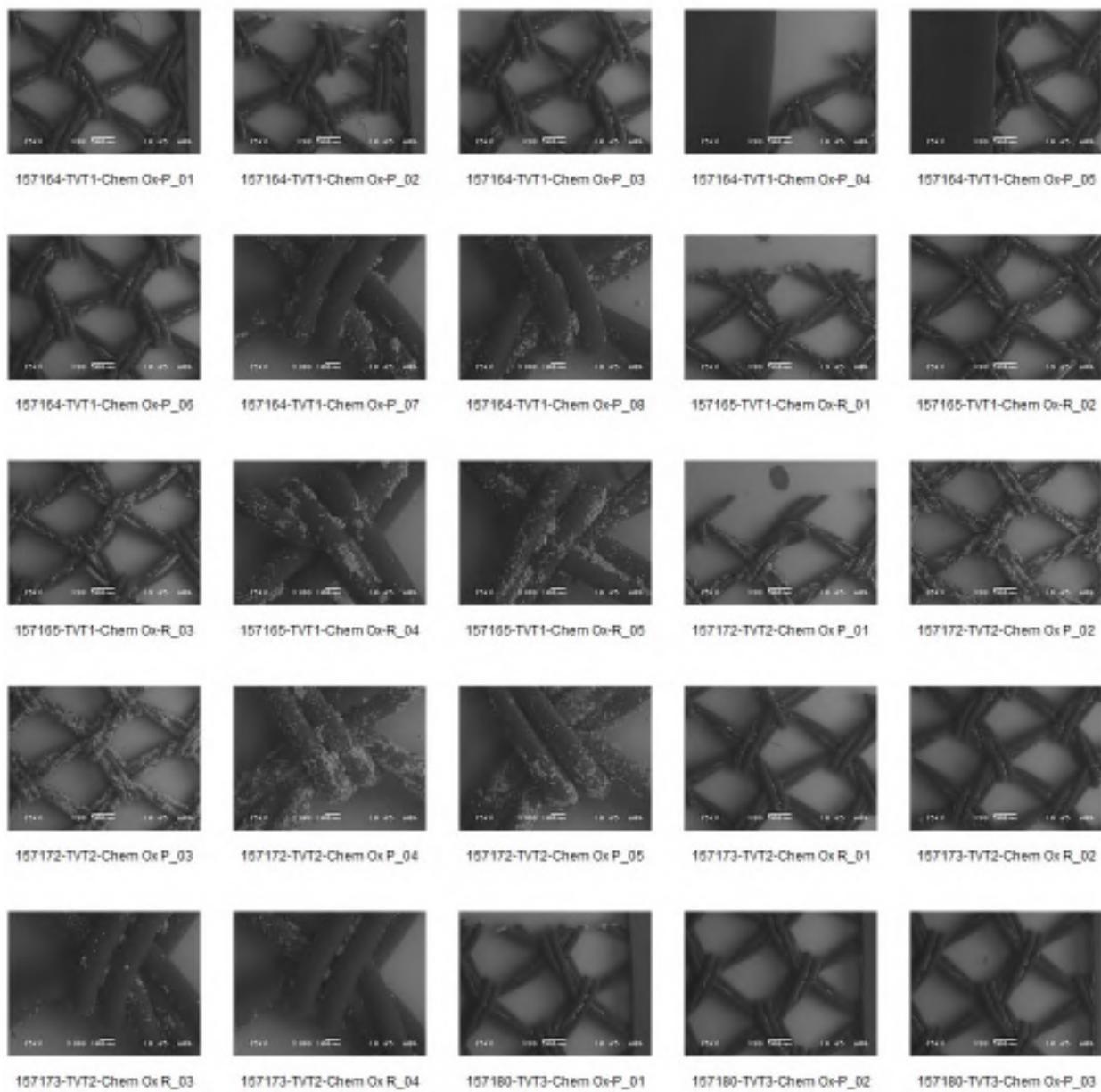
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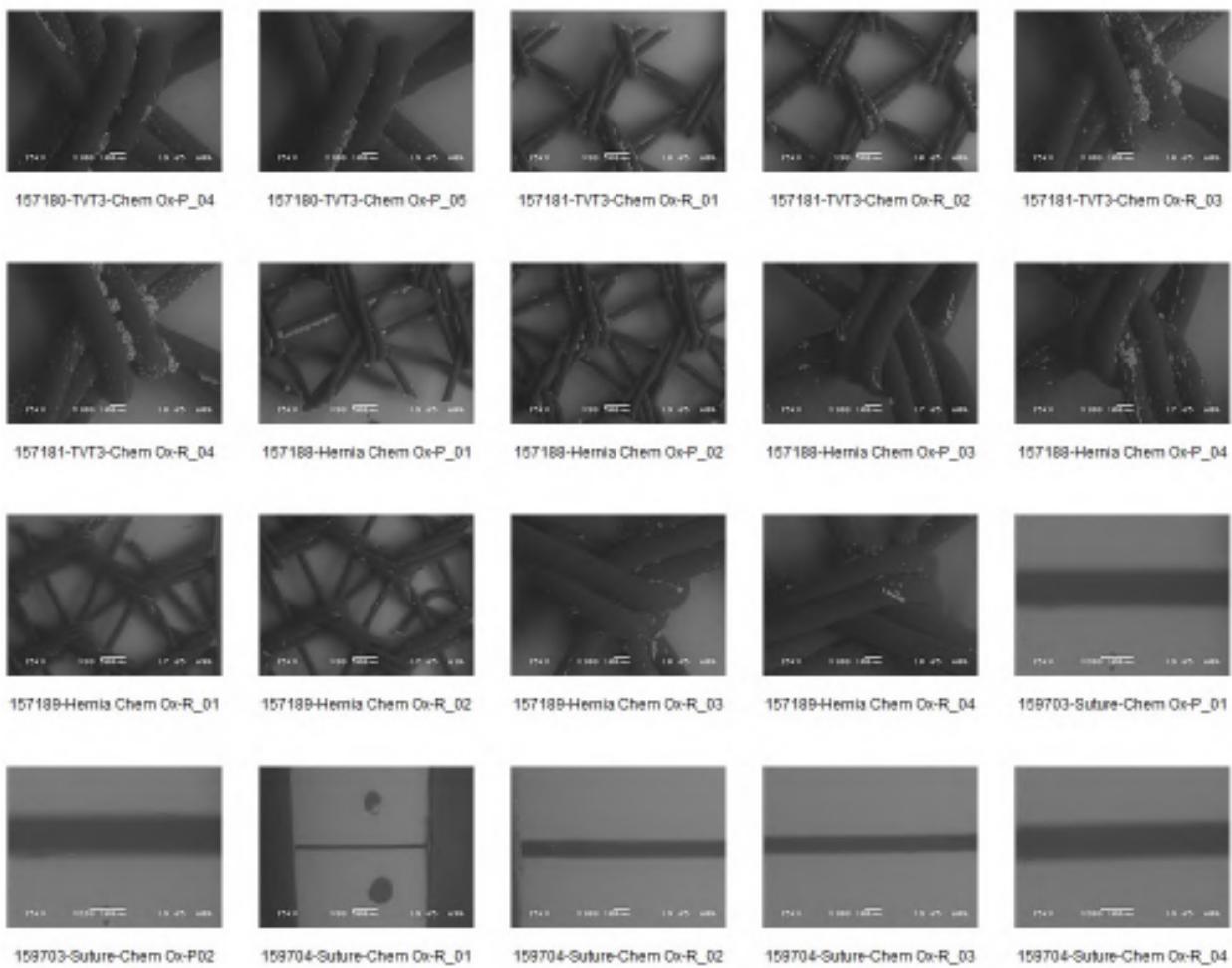
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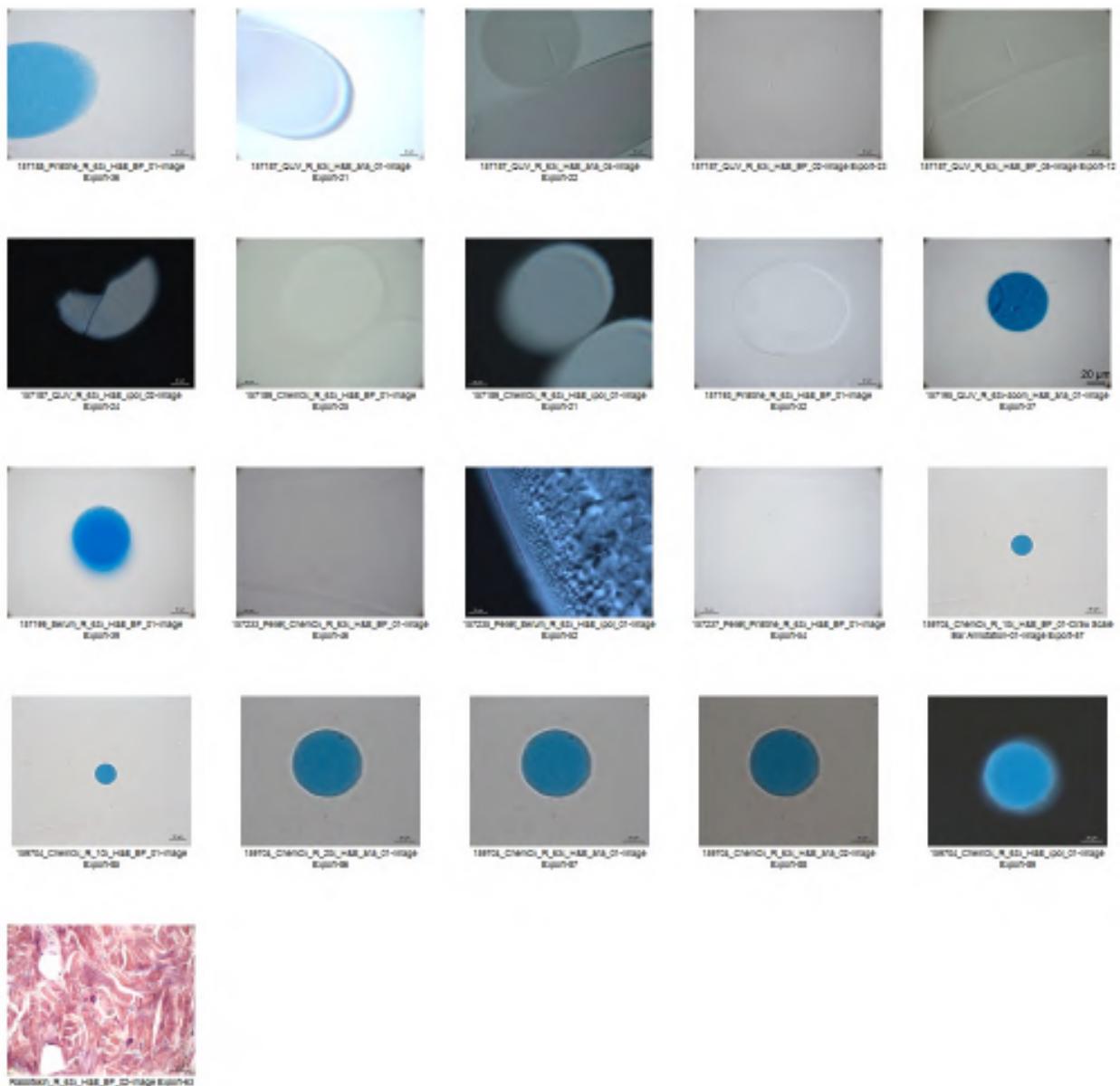






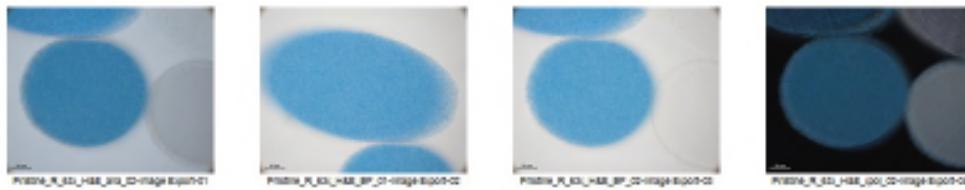


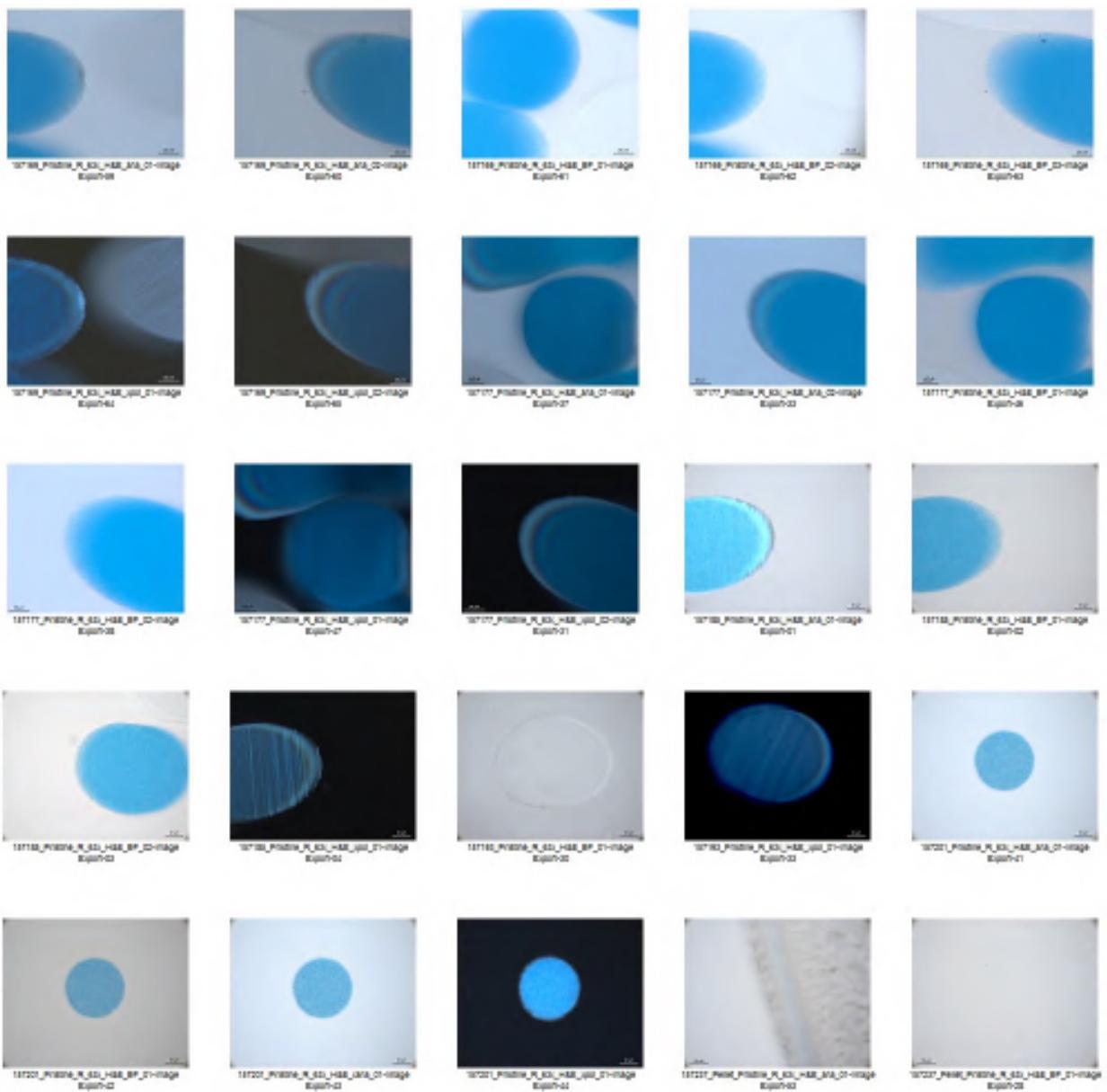


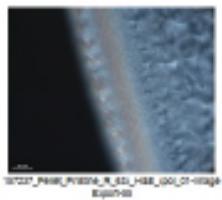












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